Efficacy of a New Full Face Mask for Noninvasive Positive Pressure Ventilation*


Previous studies have shown that noninvasive positive pressure ventilation (NPPV) improves gas exchange in acute and chronic respiratory failure. However, some patients are unable to tolerate NPPV due to air leaks around the mask, facial discomfort, and claustrophobia. A new mask that covers the entire face (Total, Respironics, Monroeville, Pa), attempts to overcome these obstacles. We studied the efficacy of NPPV via the Total face mask (TFM) in nine patients with chronic respiratory failure. In three patients, respiratory failure was due to chronic obstructive lung disease, and in six patients, it was secondary to restrictive disorders. None of the patients were previously able to tolerate NPPV via nasal (N) or nasal-oral (NO) masks. At baseline, all patients had impaired gas exchange with low PaO$_2$/FiO$_2$ (241 ± 14), elevated PaCO$_2$ (79 ± 5 mm Hg), and poor functional status (1.59 ± 1.45, on a scale of 1 to 7). After NPPV in the hospital for 7.1 ± 1.5 h per night for 22 ± 26 days, the PaCO$_2$ fell to 59 ± 3 mm Hg, and the PaO$_2$/FiO$_2$ rose to 304 ± 27. Following nocturnal NPPV via the TFM for 6.7 ± 1.5 h a night 6 ± 5 weeks after hospital discharge, sustained improvements in PaCO$_2$ (58 ± 3 mm Hg, p<0.05), PaO$_2$/FiO$_2$ (304 ± 18), and functional status (5.38 ± 1.06, p<0.05) were observed. In four patients, measurements of respiratory rate, tidal volume, minute ventilation, dyspnea, discomfort with the face mask, and mask and mouth leaks were made during 30-min sessions of NPPV applied at constant levels via all three masks (N, NO, TFM). Discomfort with the face mask (0.38 ± 0.18 vs 1.44 ± 0.34 vs 2.38 ± 0.32, p<0.05) and mask leaks (0.44 ± 0.18 vs 1.89 ± 0.39 vs 1.89 ± 0.35, p<0.05) were least during NPPV via TFM compared with the N or NO masks, respectively. Moreover, expired tidal volume was highest (804 ± 10 vs 498 ± 9 vs 537 ± 13 ml, p<0.05) and PaCO$_2$ lowest (51 ± 2 vs 57 ± 2 vs 58 ± 3, p<0.05) during NPPV via the TFM compared with N or NO masks. We conclude that NPPV delivered via a Total mask ensures a comfortable, stable patient-mask interface and improves gas exchange in selected patients intolerant of more conventional N or NO masks.

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| N=nasal; NO=nasal-oral; NPPV=noninvasive positive pressure ventilation; TFM=total face mask |

Key words: face mask; hypercapnia; noninvasive ventilation, respiratory failure

Noninvasive positive pressure ventilation (NPPV) has been shown to be an effective modality for the treatment of chronic respiratory failure in patients with severe restrictive ventilatory disorders$^1$-$^4$ and in selected patients with chronic obstructive pulmonary diseases.$^5$-$^6$ In addition, several recent studies have shown that NPPV may be an effective treatment for acute respiratory failure.$^7$-$^9$ In some patients, however, NPPV has limited efficacy because of significant problems with mask or mouth leaks, the development of facial pressure sores related to the mask, and feelings of claustrophobia.$^{9,12}$ Moreover, the requirement for frequent nurse and respiratory therapist intervention to adjust the mask so as to prevent excessive leaking, or ensure patient comfort, limits the application of NPPV in treating patients with acute respiratory failure.$^{11}$

Recently, we have had the opportunity to use a new prototypical type of face mask (Total face mask, Respironics, Monroeville, Pa) that covers the whole anterior surface of the face and delivers effective ventilation via the nasal and oral routes. This mask has a more extensive patient-mask interface and does not obstruct the patient's field of vision.

Our purpose in this study was to compare the short-term effect of NPPV delivered via this total face mask (TFM) to nasal (N) and nasal-oral (NO) masks, on ventilatory variables, gas exchange, dyspnea, mouth and mask leaks, and patient comfort with the mask. In addition, we wanted to determine the long-term efficacy of daily nocturnal NPPV via the TFM on gas exchange and functional status after several weeks.

Herein, we discuss the effectiveness of NPPV with this TFM in the treatment of patients with chronic respiratory failure.

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Table 1—Enrollment Criteria for Patients Receiving NPPV*

<table>
<thead>
<tr>
<th>Criteria</th>
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<tr>
<td>1. Severe, irreversible chronic respiratory disease</td>
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<td>2. Symptoms of nocturnal hypoventilation, including morning headache, loss of energy, enuresis, nightmares, etc</td>
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<td>3. Dyspnea at rest or increased work of breathing impairing sleep or sustained rest</td>
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<td>4. Cor pulmonale due to hypoventilation and hypoxemia unresponsive to conventional treatment</td>
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<tr>
<td><strong>Physiologic criteria</strong></td>
<td></td>
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<tr>
<td>1. Vital capacity &lt;25 percent predicted in patients with kyphoscoliosis or neuromuscular disease, but excluding patients with COPD or central hypoventilation; patients with COPD should have FEV1 &lt;25% predicted.</td>
<td></td>
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<tr>
<td>2. Pmax &lt;50 cm H2O in COPD or &lt;25 cm H2O in neuromuscular disease</td>
<td></td>
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<tr>
<td>3. PaCO2 &gt;45 mm Hg and pH &lt;7.32 persisting after appropriate treatment of airway obstruction and metabolic disturbances</td>
<td></td>
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<tr>
<td>4. Nocturnal or sleep desaturation (SaO2 &lt;88 percent) despite conventional oxygen therapy</td>
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**METHODS**

**Patient Selection**

All patients were admitted to the Ventilator Rehabilitation Unit at Temple University Hospital, Philadelphia, for evaluation and treatment of chronic respiratory failure. This noninvasive respiratory care unit evaluates patients for noninvasive mechanical ventilation, instructs patients in the use of respiratory equipment, provides whole body and respiratory muscle reconditioning, and coordinates continuing outpatient follow-up.

Prior to admission all patients were maximally treated with bronchodilators, supplemental oxygen, and on occasion theophylline for at least 48 h prior to study enrollment. All patients enrolled into the study fulfilled at least two clinical criteria and two physiologic criteria for implementation of noninvasive ventilation as shown in Table 1. Informed consent was obtained from all patients participating in the study.

**Measurement of Spirometry, Respiratory Muscle Strength, and Arterial Blood Gases**

All patients underwent standard spirometric evaluation of lung function (Gould 2400 Spirometer, Dayton, Ohio). Respiratory muscle strength was evaluated by maximal inspiratory pressure and expiratory mouth pressure as described by Black and Hyatt.13 Arterial blood gas analysis was performed using an analyzer (BG3 Analyzer, Instrumentation Laboratory, Lexington, Mass).

**Titration of NPPV**

All patients were evaluated for NPPV via a bilevel positive airway pressure device (BiPAP, Respironics, Monroeville, Pa) or a portable volume ventilator (PLV-102, Life Care, Boulder, Colo). A description of the ventilatory support system (BiPAP) has been previously well described by others.9 Appropriate settings of inspiratory and expiratory pressures and volumes and ventilatory mode (BiPAP vs portable volume ventilator) were chosen while monitoring airway pressure, airflow, and changes in tidal volume. Airway pressure was monitored at the face mask via a pressure transducer (Validyne, range ±100 cm H2O, Northridge, Calif). Changes in airflow were measured by a pneumotachograph (Hans Rudolph, Kansas City, Mo) placed between the mask and the exhalation valve, and inspired and expired volumes were recorded by integration of the airflow signal (Gould Recorder ES 1000, Dayton, Ohio). Titration of inspiratory and expiratory pressures for patients using the ventilatory support system and of ventilator-delivered tidal volume for patients using a volume ventilator were determined by achieving an expired minute ventilation of at least 20 percent over spontaneous ventilation while simultaneously improving gas exchange (increased PaO2/FIO2 and lowered PaCO2), and ensuring patient-ventilator synchrony.

Patients were chosen to receive the ventilatory support system or noninvasive ventilation via a volume ventilator based on their degree of comfort with each mode, and the ability to increase minute ventilation and improve gas exchange. After the initial evaluation for noninvasive ventilation, seven patients received the ventilatory support system and two patients required a portable volume ventilator.

**Masks for NPPV**

Noninvasive mechanical ventilation was applied in each patient via an N CPAP mask (Respironics), an NO mask (Vitalog, Vital Signs), and the prototype TFM (Total, Respironics). A close-up view of the inside and outside of the TFM is shown in Figure 1.
Assessment of Functional Status, Discomfort With the Face Mask, Dyspnea, and Mask Leaks

Functional status was evaluated and graded with the following scale: 1=impaired cognition; 2=awake, alert, and oriented; 3=chair bound; 4= independant in activities of daily living; 5=ambulatory, but homebound; 6=performs non-self-care activities at home (ie, cooking, housework, etc); and 7=performs activities outside of home.

The patient’s level of discomfort with the face mask was scaled as follows: 0=comfortable, 1=uncomfortable, and 2=very uncomfortable.

The level of dyspnea was scored in arbitrary units with a four-point scale: 0=no dyspnea; 1=mild dyspnea; 2=moderate dyspnea; and 3=severe dyspnea.

The degree of air leakage for each mask was also scaled with a four-point scale using arbitrary units: 0=no leaks; 1=one to three leaks per minute; 2=three to six leaks per minute; and 3=greater than six leaks per minute.

Experimental Protocols

Comparative Efficacy of the Various Masks During Short-term NPPV: Baseline measurements of ventilatory variables (ie, minute ventilation, tidal volume, respiratory rate), and arterial blood gas tensions were performed in four patients during eupneic ventilation. All patients then underwent three NPPV trials of 20 to 30 min duration to ensure stability during noninvasive ventilation using each of the three different masks (TFM, N, NO) in random order. After initial titration of pressure (BiPAP) or volume (PLV-102), to achieve ventilation goals as previously outlined, levels of ventilation remained identical during each trial with the three different face masks. At the end of each trial, arterial blood gas analysis was performed and the patients were queried with regard to their level of comfort with the mask, and their perception of dyspnea when using each of the masks. In addition, a semiquantitative analysis of air leaks during NPPV with each mask was determined.

Long-term Efficacy of NPPV via the TFM: In nine patients, NPPV was delivered via the TFM as an inpatient for 22±26 days, 7.1±1.5 h a night, and as an outpatient for 6±5 weeks, 6.7±1.5 h a night. Arterial blood gases and functional status were measured at admission, discharge from the hospital, and at follow-up. Respiratory mechanics (spirometry and respiratory muscle pressures) were also obtained in follow-up.

Statistical Analysis

An analysis of variance was used to compare ventilatory variables, arterial blood gases, mask leaks, discomfort with the face mask and level of dyspnea between eupnea, and NPPV via the various masks. The Student’s t test was used to determine whether a significant relationship existed between the values for arterial blood gases, respiratory mechanics, and functional status at baseline, hospital discharge, and follow-up. A p value <0.05 was considered statistically significant.

RESULTS

Patient characteristics are shown in Table 2. Three patients had severe obstructive lung disease, and six patients had severe restrictive disorders. The patients’ ages ranged from 44 to 81 years. Three of the nine patients suffered from acute superimposed on chronic respiratory failure that had necessitated recent (within 6 months of the study) endotracheal intubation and mechanical ventilation. The remaining patients had a more gradual, progressive worsening of their respiratory status. Five patients had evidence of cor pulmonale with a right-sided third heart sound, elevation in the pulmonic component of the second heart sound, peripheral edema, and evidence of right ventricular dysfunction by two-dimension echocardiography. All patients had severe derangements in lung mechanics with an FVC (mean±SD) of 0.95±0.44 L, and FEV1 of 0.57±0.18 L.

Comparative Efficacy of the Various Masks During Short-term NPPV

Arterial blood gas analysis for each patient while breathing spontaneously and during NPPV with each of the three masks is shown in Figure 2. The mean PaO2/FiO2 values during NPPV with each of the masks were higher (360±25, N; 346±19, NO; and 358±24, TFM) compared with eupnea (315±19, p<0.05), but not different among the different mask types. In contrast, mean PaCO2 was significantly lower during NPPV with each of the masks (57±2, N; 58±3, NO; and 51±2, TFM) compared with eupnea (66±4 mm Hg, p<0.05), but PaCO2 was least with NPPV delivered via the TFM (p<0.01). The pH was greater during NPPV with all three masks compared with eupnea, but was greatest during NPPV.

### Table 2—Patient Characteristics

<table>
<thead>
<tr>
<th>Patient No.</th>
<th>Disease Causing Respiratory Failure</th>
<th>Age, yr</th>
<th>History of Acute Respiratory Failure</th>
<th>Presence of Cor Pulmonale (% Predicted)</th>
<th>FVC, L (% Predicted)</th>
<th>FEV1, L (% Predicted)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>COPD, obesity-hypoventilation</td>
<td>76</td>
<td>Yes</td>
<td>Yes</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>2</td>
<td>Severe kyphoscoliosis</td>
<td>44</td>
<td>No</td>
<td>No</td>
<td>0.75 (22)</td>
<td>0.72 (26)</td>
</tr>
<tr>
<td>3</td>
<td>Thoracoplasty, kyphoscoliosis</td>
<td>81</td>
<td>Yes</td>
<td>Yes</td>
<td>0.90 (33)</td>
<td>0.64 (34)</td>
</tr>
<tr>
<td>4</td>
<td>Severe kyphoscoliosis</td>
<td>55</td>
<td>No</td>
<td>No</td>
<td>0.43 (16)</td>
<td>0.32 (16)</td>
</tr>
<tr>
<td>5</td>
<td>Diaphragm paralysis</td>
<td>68</td>
<td>Yes</td>
<td>Yes</td>
<td>0.74 (28)</td>
<td>0.72 (36)</td>
</tr>
<tr>
<td>6</td>
<td>Severe kyphoscoliosis, postpolio syndrome</td>
<td>72</td>
<td>No</td>
<td>Yes</td>
<td>0.69 (41)</td>
<td>0.52 (38)</td>
</tr>
<tr>
<td>7</td>
<td>Severe kyphoscoliosis, postpolio syndrome</td>
<td>56</td>
<td>No</td>
<td>Yes</td>
<td>0.93 (27)</td>
<td>0.81 (31)</td>
</tr>
<tr>
<td>8</td>
<td>COPD</td>
<td>75</td>
<td>Yes</td>
<td>Yes</td>
<td>1.88 (48)</td>
<td>0.36 (14)</td>
</tr>
<tr>
<td>9</td>
<td>COPD</td>
<td>62</td>
<td>No</td>
<td>No</td>
<td>1.26 (36)</td>
<td>0.45 (17)</td>
</tr>
<tr>
<td>Mean</td>
<td></td>
<td>66</td>
<td>±12</td>
<td>±0.44</td>
<td>0.57</td>
<td>0.18</td>
</tr>
</tbody>
</table>

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with the TFM (7.41 vs 7.34, p<0.05).

The comparative effect of NPPV with the three different masks on ventilatory variables in each pa-
tient is shown in Table 3. Respiratory rate tended on
average to be lower during NPPV compared with
eupnea, but was not statistically significant. Expired
minute volumes were also greater with NPPV when
compared with eupnea, but not different among the
three masks. Expired tidal volumes were significa-
cantly greater with NPPV when compared with eupnea
(p<0.05), and the exhaled tidal volume was greatest
with the TFM (p<0.05). Inspired tidal volumes, in-
spiratory time and mean inspiratory flow, and duty
cycle were significantly increased with the use of
NPPV, when compared with eupnea (Table 3). Among
the three masks, the duty cycle was least with the
TFM (p<0.05).

Figure 3 shows the degree of air leaks and the levels
of discomfort with the face mask and dyspnea among
the three masks in NPPV. There was a significant
reduction (p<0.003) in air leakage when NPPV was
delivered via the TFM (0.44±0.18) when compared
with the N (1.89±0.39) and NO masks (1.89±0.35).
The level of discomfort with the NPPV face mask was
also least with the TFM (p<0.02). Finally, dyspnea
was also significantly less in NPPV with the TFM
(p<0.02) and N mask (p<0.05) in comparison to
eupnea and NPPV with the NO mask.

Table 3—Inspired and Expired Ventilatory Variables During Eupnea and NIPPV With All Masks

<table>
<thead>
<tr>
<th>Mask</th>
<th>RR, b/m</th>
<th>Inspired Vt, ml</th>
<th>Inspiratory Vt, L/m</th>
<th>Expired Vt, ml</th>
<th>Expired Vt, L/m</th>
<th>Ti, s</th>
<th>VT/Ti, L/s</th>
<th>Ti/Ttot</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eupnea</td>
<td>22±5</td>
<td>331±1</td>
<td>6.9±0.9</td>
<td>312±7</td>
<td>7.7±1.3</td>
<td>0.80±0.03</td>
<td>442±7</td>
<td>0.35±0</td>
</tr>
<tr>
<td>N</td>
<td>16±2</td>
<td>488±9*</td>
<td>8.3±0.5*</td>
<td>1026±90*</td>
<td>16.2±3.7</td>
<td>1.74±0.08*</td>
<td>622±10*</td>
<td>0.46±0.1*</td>
</tr>
<tr>
<td>NO</td>
<td>16±2</td>
<td>537±13*</td>
<td>8.8±0.5*</td>
<td>1352±83*</td>
<td>15.8±2.6</td>
<td>1.74±0.07</td>
<td>742±15</td>
<td>0.49±0.1*</td>
</tr>
<tr>
<td>TFM</td>
<td>16±2</td>
<td>804±10*†</td>
<td>12.0±1.6*</td>
<td>1137±24*</td>
<td>18±3.7</td>
<td>1.40±0.02</td>
<td>839±16†</td>
<td>0.40±0†</td>
</tr>
</tbody>
</table>

*p<0.05 compared with eupnea.
†p<0.05 compared with nasal and nasal-oral mask.
ment in oxygenation and ventilation during NPPV compared with spontaneous breathing. After daily NPPV, as an inpatient (7.1 ± 1.5 h per night) for 22 ± 6 days, patients had an increase in PaO₂/FI₂O₂ (304 ± 27 vs 241 ± 14, p < 0.05) with a simultaneous reduction in PaCO₂ (59 ± 3 mm Hg vs 79 ± 5, p < 0.05) during daytime spontaneous breathing compared with hospital admission. After 6 ± 5 weeks following hospital discharge, using nightly NPPV as an outpa-

tient for 6.7 ± 1.5 h a night, the improvements in daytime gas exchange were maintained compared with hospital discharge (PaCO₂ 58 ± 3 mm Hg vs 59 ± 3) and PaO₂/FI₂O₂ (304 ± 18 vs 304 ± 27).

Functional status before NPPV for the nine patients was 1.89 ± 1.45 (range, 1 to 7). Following no-
turnal NPPV as an outpatient, the functional status increased to 5.38 ± 1.06 (p < 0.05). There was no signif-
icant effect of NPPV via the TFM on spirometry (FEV₁, 0.58 ± 0.19 L; FVC, 0.95 ± 0.53 L; vs FEV₁, 0.60 ± 0.21 [p = 0.87]; FVC, 1.18 ± 0.76 L [p = 0.52]) or maximum inspiratory (40 ± 12 vs 27 ± 13 cm H₂O [p = 0.13]) and expiratory (58 ± 21 vs 38 ± 13 cm H₂O [p > 0.07]) mouth pressures compared with baseline.

**Side Effects of the TFM**

The side effects of TFM ventilation were minor and included mild irritation over the chin due to improper padding of the inferior margin of the face mask, and overtightening of the TFM causing the anterior surface of the mask to compress the nose during expiration. No patient complained of eye or face irritation, no patient demonstrated gastric distention, and no patient developed rhinitis, claustrophobia, or panic.

**DISCUSSION**

There was a significant improvement in gas exchange short term during NPPV with all three masks; however, the reduction in PaCO₂ was greatest when NPPV was delivered with the TFM. This is attributed to the observation that the increases in expired tidal volume and minute ventilation were greatest with the use of the total face mask. In addition, dyspnea, discomfort with the face mask, and level of mask or mouth leaks were least during NPPV with the TFM compared with the N or NO masks. Moreover, there was a significant improvement in gas exchange and functional status with daily use of NPPV with the TFM and this improvement was sustained over the period of follow-up.

The results of our study demonstrate that NPPV via a TFM is an effective way of delivering noninvasive ventilation while simultaneously minimizing the development of mask leaks and improving patient comfort. Similarly, this form of face mask is much easier to use and is less likely to become

![Figure 4](http://journal.publications.chestnet.org/pdfaccess.ashx?url=/data/journals/chest/21701/ on 06/25/2017)
dislodged or need frequent readjustment to maintain an adequate seal.

Because the TFM covers the entire face, one would think that this would worsen feelings of claustrophobia rather than improve it. However, in three patients in whom claustrophobia limited tolerance of the NO mask, this sensation was avoided with the use of the TFM. Potential explanations for the reduction in claustrophobia while using the TFM include the following: an unobstructed patient field of vision; the ability to verbally communicate; and the sensation of air flowing over the entire face while using the mask.

Conceivably, allowing the patients to see and verbally communicate while in the TFM may have lessened the patient's feelings of isolation, and further improved the patient's tolerance of noninvasive ventilation.

Many patients with pulmonary conditions express a subjective decrease in the sensation of dyspnea when cold or flowing air is directed to the face. Breathless patients commonly request a fan or to be placed near an open window to alleviate breathlessness. Schwartzstein et al.\(^{14}\) have shown a significant reduction in the sensation of dyspnea when normal subjects have cold air directed to the cheeks while breathing against an inspiratory resistive load. Di Giorgio and Giulio showed similar results in normal subjects breathing through a range of linear resistive loads from 1.5 to 15 cm H\(_2\)O when ambient air produced by a fan was applied to the subject's face.\(^{15,16}\)

Although, the mechanism(s) responsible for the reductions in dyspnea when cold or ambient air is directed to the face are unknown, Schwartzstein and colleagues\(^{14}\) hypothesized that stimulation of afferent trigeminal nerve receptors may have altered the central perception of breathlessness. It is conceivable that stimulating facial cutaneous receptors via continuous airflow during NPPV via the TFM may have contributed in part to a reduction in the patient's sensation of dyspnea while using this mask. Whatever the mechanism(s), however, all patients reported the greatest reduction in dyspnea during noninvasive ventilation when using the TFM.

Complications that arose using the TFM ventilation were minimal. Since this form of face mask has a much larger volume, it has a significantly greater amount of dead space compared with other commercially available forms of N or NO masks. The dead space volume of the TFM is 1,500 ml, compared with 105 ml with the N mask and 250 ml with the NO mask (not accounting for a reduction in dead space by facial structures when wearing the mask). However, in no patient did this increased amount of dead space pose a problem by either increasing the patient's sense of dyspnea or adversely affecting blood gas tensions.

To minimize the potentially adverse effects of an increased dead space with the full face mask, the manufacturer recommends a base flow sufficient to maintain an expiratory positive airway pressure of 4 or 5 cm H\(_2\)O at all times. In addition, there are two small bore orifices in the superior aspect of the mask to act as exhalation valves. In patients discharged home from the hospital with the mask, oxygen was administered by a compressed gas source to ensure gas flow if electrical failure would occur. Moreover, all masks were equipped with quick release straps to ensure immediate removal if needed. All of our patients were awake and alert, were able to provide their own self-care, and were knowledgeable about the benefits and potential hazards of using a TFM. We followed the above-stated recommendations and found in all patients while using this mask a reduction in the sense of dyspnea, a lowering in the arterial carbon dioxide, and an improvement in their functional status. No complications during short- or long-term use at home were observed in our patients, and the above recommendations for use are strongly encouraged.

Other complications such as eye irritation and gastric distention would be expected to be more common during noninvasive ventilation with the TFM. However, eye irritation and gastric distention were not observed in any subject and may further reflect an improvement in patient ventilator synchrony with the use of a more comfortable mask.

Although NPPV via N, oral, or NO routes has been shown to be effective in improving ventilatory status in patients with acute or chronic respiratory failure, these therapies are limited by being labor intensive. When noninvasive ventilation is applied to critically ill patients with acute respiratory failure, mask leaks, patient communication, and patient comfort necessitate constant nursing and/or respiratory therapy intervention for mask repositioning and patient monitoring. Chevrolet and colleagues\(^{11}\) reported that patients with COPD receiving NPPV required 90 to 100 percent of one ICU nurse's time to provide emotional support, give direct personal care, and adjust the face mask. These constant demands on nursing care and mask repositioning limit the broad application of this technique for patients in acute respiratory failure. A face mask that is more comfortable for the patient but requires less adjustment to minimize mask or mouth leaks could substantially reduce the labor intensiveness of NPPV.

Mask or mouth leaks may also have a negative effect on gas exchange and impair the effectiveness of NPPV in avoiding endotracheal intubation. In studies examining NPPV in acute respiratory failure, inability to improve gas exchange, or poor patient tolerance of the mask, results in 10 to 50 percent of pa-
tients failing therapy and requiring endotracheal intubation. Improvements in face mask design that improve patient tolerance and increase alveolar ventilation by minimizing leaks may have a significant impact on NPPV being successful in patients with acute respiratory failure. Recently, in two of our patients, noninvasive ventilation with the TFM was used in the ICU when the patients originally presented in acute respiratory failure. Although, N and NO masks were poorly tolerated by these two patients because of feelings of claustrophobia, significant mouth leaks, and patient-ventilation dysynchrony, noninvasive ventilation via the TFM was easily applied, was well tolerated by the patients, and was not complicated by significant leaks even when used for extended periods of time (ie, continuously for 10 to 12 h). In one of the two patients, noninvasive ventilation via the TFM was possible despite the presence of a nasogastric tube for administration of medications without adversely affecting the patient mask seal.

In summary, we have shown that NPPV via a TFM in selected patients with chronic respiratory failure may improve comfort, minimize air leakage from the mask-face interface, and improve alveolar ventilation. Furthermore, we suggest that this form of mask may be effective in patients suffering from acute respiratory failure who are candidates for noninvasive mechanical ventilation in a controlled environment such as the ICU. As our data show, the face mask used for noninvasive ventilation may have an important impact on the degree of face mask or mouth leaks, patient tolerance, and overall efficacy of noninvasive ventilation. Additional larger, prospective, and randomized clinical trials using the various forms of face masks are currently needed to confirm the most effective mask for delivering NPPV.

ACKNOWLEDGMENTS. We would like to acknowledge the donation of the Total masks used during this study by Respironics, and the secretarial assistance of Darlene Macon.

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