Preliminary Report of Laryngeal Phonation During Mechanical Ventilation Via a New Cuffed Tracheostomy Tube

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OBJECTIVE: To study the safety, efficacy, patient tolerance, and patient satisfaction of the Blom Tracheostomy Tube and Speech Cannula (Pulmodyne, Indianapolis, Indiana), a new device that allows the patient to speak while the tracheostomy tube cuff is fully inflated. METHODS: With 10 tracheostomized mechanically ventilated patients we recorded ventilator settings and physiologic variables at baseline with patient's usual tracheostomy tube, then with the Blom Tracheostomy Tube and the Blom standard (non-speech) cannula, and then during three 30-min trials of the Blom Speech Cannula. During the Blom Speech Cannula trials we assessed the subjects' success in phonation (eg, sentence length and volume). RESULTS: Nine of the 10 subjects achieved sustained audible phonation and were very satisfied with the device. CONCLUSIONS: The Blom Speech Cannula appears to be safe, effective, and well tolerated in tracheostomized mechanically ventilated patients while maintaining full cuff inflation. *Key words: tracheostomy; Speech Cannula; laryngeal phonation; mechanical ventilation; cuffed tracheostomy tube.* [Respir Care 2010;55(12):1661–1670.

Introduction

Compromised communication can be emotionally taxing for tracheostomized patients receiving mechanical ventilation. This patient group is unable to produce voice because the inflated tracheostomy tube cuff seals the airway inferior to the larynx and thus prevents air flow across the vocal folds. As several studies have shown,[1-4] communication problems associated with mechanical ventilation create feelings of insecurity, anxiety, fear, and frustration, which result primarily from the impaired ability to communicate emotional concerns to family members, friends, and clinicians, and to participate actively in conversations. Some patients have even stated that if they were not able to communicate or participate in everyday activities, they would prefer to die.[4]

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Patients receiving mechanical ventilation through a cuffed tracheostomy tube cannot phonate. During inspira-

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Ms Appel has disclosed a relationship with Pulmodyne. The other authors have disclosed no conflicts of interest. This research was partly supported by Pulmodyne, which supplied the Blom Tracheostomy Tubes and Speech Cannulas and provided the results of Pulmodyne's laboratory testing.

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tion, air is directed through the tracheostomy tube to the lungs, and during expiration it is directed through the tracheostomy tube back to the ventilator, not up through the vocal folds. One method to allow these patients to talk is to deflate the cuff and place a one-way speaking valve in line with the ventilator tubing. A one-way speaking valve allows the gas to enter the lungs during inhalation, and redirects the exhaled air past the vocal folds, thereby allowing speech. Unfortunately, using a one-way speech valve mandates deflating the tracheostomy tube cuff, which creates several challenges for the patient and practitioner. First, cuff deflation is contraindicated or not well tolerated by many patients. Deflating the cuff can also result in aspiration of secretions. Furthermore, cuff deflation results in ventilator alarms, many of which cannot be disabled or safely silenced when exhalation is directed through the upper airway and not back to the ventilator's flow sensors.

A new talking tracheostomy tube with an optional Speech Cannula that permits exhalation via the upper airway during mechanical ventilation with a fully inflated cuff was recently developed and is the subject of this preliminary investigation. Our goal was to provide first-round observations of the efficacy and safety of the Blom Tracheostomy Tube and Speech Cannula (Pulmodyne, Indianapolis, Indiana) in ventilator-dependent tracheostomized patients. After the trials we asked the subjects about their satisfaction with the device.

Methods

Subjects

The subjects were recruited in and the study performed in the Department of Anesthesiology and Reanimation, Ibn-i Sina Hospital, Ankara, Turkey, and in the Department of Anesthesiology and Reanimation, Atatürk Chest Disease and Thoracic Surgery Education and Research Hospital, Ankara, Turkey. The study was approved by the institutional review board, and all subjects signed the approved consent form before participating in the study.

The inclusion criteria were: $\geq$ 21 years old; weight $\geq$ 30 kg; awake; alert; cooperative; able to follow simple commands; and able to understand and sign the consent form. All the subjects were ventilator-dependent and required a fully inflated tracheostomy tube cuff. The medical necessity for mechanical ventilation was determined by each subject's primary physician team. All the subjects were able to respond to simple orientation questions via "mouthing" with intact, functional speech structures (lips, tongue, and jaw), as assessed by a standard oral motor exam, and had watery to moderately thick secretions.

The exclusion criteria were: use of a special/custom tracheostomy tube (extra proximal length, extra distal length, or foam cuff); known upper-airway obstruction that limited or prevented exhalation through the upper airway; an excessively dilated tracheostoma; F_{IO_2} requirement $>$ 60%; PEEP $>$ 10 cm H_2O; tenacious or copious tracheal secretions that required suctioning $>$ 3 times per hour. Tenacious secretions were defined as those that were still attached to the inner surface of the suction catheter after tracheal suctioning and that could not be easily removed by suctioning water or saline through the catheter. There were no exclusions regarding ventilator type or ventilation mode; subjects could be on a standard or portable ventilator, using any pressure or volume ventilation mode.

Table 1 shows the subject demographics, medical diagnoses, and ventilation modes. There were 5 female and 5 male participants. Their age range was 27–80 years.

Table 1. Subject Demographics, Medical Diagnoses, and Ventilation Modes

Subject	Sex	Age (y)	Medical Diagnosis	Ventilation Mode	Days on Ventilation	Ventilator Model
1	F	80	Respiratory failure due to muscle weakness	SIMV	65	Hamilton Galileo
2	F	27	C4-5 translocation with quadriplegia secondary to motor vehicle accident	CPAP/PS	50	Dräger Evita 4
3	F	55	Pulmonary embolus	CPAP/PS	55	Dräger Evita 4
4	F	47	Quadriplegia secondary to trauma	CPAP/PS	70	Dräger Evita 4
5	M	36	Myasthenia Gravis	CPAP/PS	55	T-Bird AVS3
6	M	55	COPD and pneumonia	BPAP	28	Respironics Esprit
7	F	72	COPD and heart failure	SIMV	48	Respironics Esprit
8	M	72	COPD	SIMV	19	T-Bird AVS 3
9	M	51	Respiratory failure secondary to trauma	CPAP/PS	16	Dräger Evita 4
10	M	52	COPD and heart failure	SIMV	9	Respironics Esprit

SIMV = synchronized intermittent mandatory ventilation
CPAP = continuous positive airway pressure
PS = pressure support
BPAP = bi-level positive airway pressure

The duration of mechanical ventilation ranged from 9 to 70 days. Four subjects used synchronized intermittent mandatory ventilation, five used continuous positive airway pressure (CPAP) plus pressure support, and one used bi-level positive airway pressure (BPAP) with an inspiratory pressure of 8 cm H_2O and an expiratory pressure of 4 cm H_2O. The latter patient's attending physician opted for BPAP because it allows a small cuff leak and therefore a larger air leak without triggering ventilator alarms, which allowed the patient to speak intermittently.

Study Protocol and Data Collection

Prior to exchanging a subject's current tracheostomy tube with the experimental tube, we recorded the ventilator manufacturer and model, ventilation mode, set tidal volume or pressure control/pressure support level, set respiratory rate, inspiratory time, PEEP, CPAP, peak ventilating pressure, upper pressure limit, S_{pO_2}, heart rate, blood pressure, and respiratory rate.

The United States Food and Drug Administration Review Panel recommended the number and duration of the trials. We did not collect data on ventilator weaning practices or previous attempts to wean these subjects, as this was not among our study goals.

Subject Preparation

The Blom Tracheostomy Tube we tested can be inserted percutaneously, surgically, or by changing from another brand/style of tracheostomy tube, as determined by the physician and facility protocol. All 10 subjects initially had a different brand of tracheostomy tube. Each subject's current tracheostomy tube was removed and replaced with a Blom Tracheostomy Tube of equivalent dimension. The tracheostomy tube change was done by the physician investigator, using standard-of-care procedures for this process. The same Blom Tracheostomy Tube was left in until the 3 Speech Cannula trials were completed.

We recorded the ventilator settings and physiologic variables before changing from the patient's usual tracheostomy tube, during the period with the Blom Tracheostomy Tube and the Blom standard (non-speech) cannula, and during the trials with the Blom Speech Cannula. We inspected each Speech Cannula's structure and the functioning of its valves prior to placement. Once the subject was stable and comfortable following the change to the Blom Tracheostomy Tube, we suctioned the airway at least once, below the cuff.

Immediately after the Speech Cannula was placed, we:

- Verified upper-airway air flow by listening carefully at the subject's mouth for exhaled air flow and placing a tissue in front of the subject's mouth and observing it for movement.
- Asked the subject to forcibly exhale and felt for air flow out of the mouth and nose.
- Asked the subject to focus on the expired air flow and its duration coming out the mouth/nose on each expiratory cycle of the ventilator.
- Asked the subject to produce an audible sustained "ah" sound, then to count out loud, then to say short multi-syllable phrases.

Throughout each 30-min trial the subject's airway was suctioned through the Speech Cannula, as needed, and we recorded and described all these suctioning events. At the end of each 30-min trial the Speech Cannula was removed and a Blom standard cannula was inserted. The trials were separated by 2-hour intervals. A new Speech Cannula was used for each trial. With every subject the three 30-min trials were conducted on the same day. We continuously supervised each trial and closely monitored airway patency, physiologic stability, and phonation. We also recorded each subject's tolerance of and subjective satisfaction with the device.

Following completion of the 30-min trials, the subject was refitted with a new cuffed tracheostomy tube of the same brand and size used prior to the trials.

Blom Tracheostomy Tube

The Blom Tracheostomy Tube (Fig. 1) has a thin polyvinyl chloride cuff and a fenestration, and it can use the Blom standard (non-speech) cannula or the Blom Speech Cannula, both of which clip on to the tracheostomy tube (Fig. 2). Also now available is a disposable cannula that allows for the removal of secretions from above the cuff, though the disposable cannula was not available during this study.

The Blom Tracheostomy Tube's fenestration allows air flow to the upper airway when the Speech Cannula is used (see Fig. 1). The fenestration is strategically located just above the cuff, such that, when inflated, the cuff prevents the fenestration from contacting the tracheal mucosa. The fenestration is rounded, with smooth edges.

Blom Standard and Speech Cannulas

The standard (non-speech) cannula (see Fig. 1) should be used when the Speech Cannula is not being used. Both the standard cannula and the Speech Cannula have a standard International Organization for Standardization 15-mm hub and "telephone jack" style clips that lock with an audible click and securely fasten and release with minimal pressure on the tracheostomy tube (see Fig. 2). These clips reduce the risk of the cannula disconnecting from the tracheostomy tube. Because these clips are unique to the

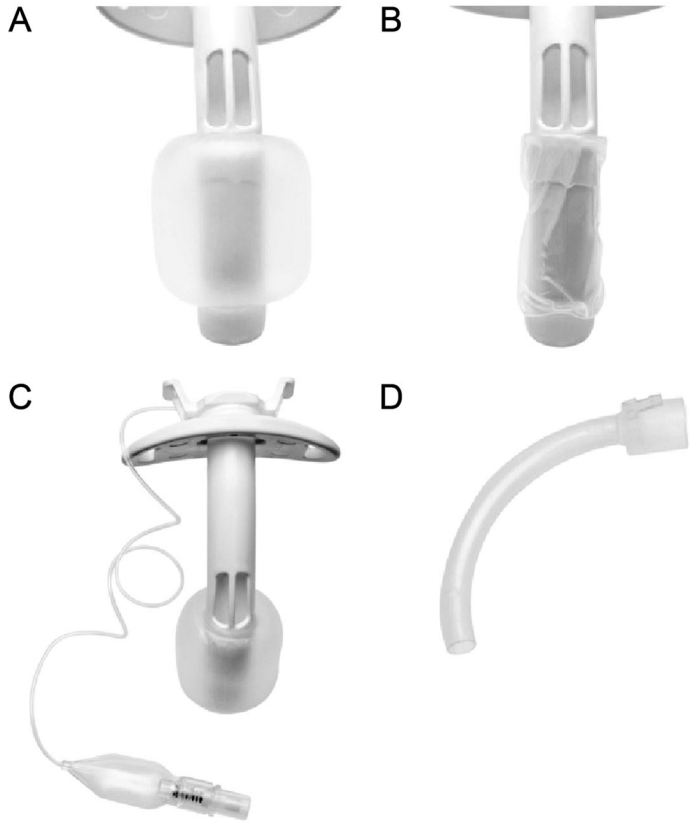

Fig. 1. A: The Blom Tracheostomy Tube with cuff inflated. B: With cuff deflated. C: The Blom Tracheostomy Tube. D: The Blom standard (non-speech) cannula.

Blom Tracheostomy Tube, the Blom cannulas will not connect to other tracheostomy tube brands.

The Blom Speech Cannula (see Fig. 2 and 3) is made of silicone and has 2 valves. Inspiratory pressure opens the flap valve and closes (expands) the bubble valve, which seals the fenestration, so all the inspiratory air goes to the lungs. As inspiration ends, the flap valve closes. Expiratory pressure collapses the bubble valve, which unblocks the fenestration and directs all the exhaled air to the upper airway to allow phonation.

Exhaled Volume Reservoir

The Exhaled Volume Reservoir (Fig. 4) is a separate component that assists in preventing false low-expiratory-minute-volume alarms that would occur because the exhaled air is directed through the upper airway instead of back to the ventilator. The Exhaled Volume Reservoir, which is compatible with most ventilators, is a small silicone bellows system that expands and traps gas during inspiration, then returns the gas to the ventilator to be measured as exhaled volume during expiration. The Exhaled Volume Reservoir can be placed at the end of the expiratory circuit, adjacent to the exhalation inlet port (if the ventilator measures the exhaled volume at the ventilator), or between the flow sensor and the subject (if the volume is measured by a proximal flow sensor). The Blom Tracheostomy Tube's directions indicate that the Speech Cannula should be used under supervision, and the Exhaled Volume Reservoir should be used only during speech-cannula use, and removed when the Speech Cannula is not in use.

Investigator Training on Blom Speech Cannula Use

All the investigators in this study were trained with written tutorials and oral presentations by the product inventor and/or two of the primary investigating speech-language pathologists regarding the features, benefits, function, candidacy criteria, and safety information on the Blom Tracheostomy Tube, Speech Cannula, and Exhaled Volume Reservoir prior to using them with the consented subjects. The subjects were supervised at all times by the investigators while using the Blom Tracheostomy Tube and Speech Cannula.

Results

Table 2 summarizes the events, changes in physiologic and ventilation variables, and interventions during the tri-

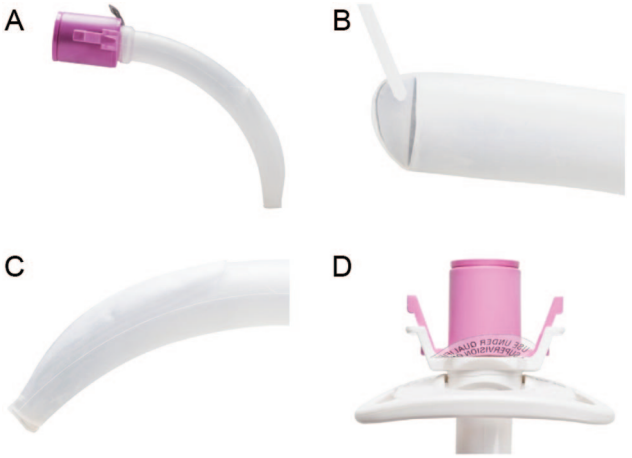

Fig. 2. A: The Blom Speech Cannula. B: Flap valve at distal end of Speech Cannula. C: Bubble valve. D: Speech cannula clipped into tracheostomy tube.

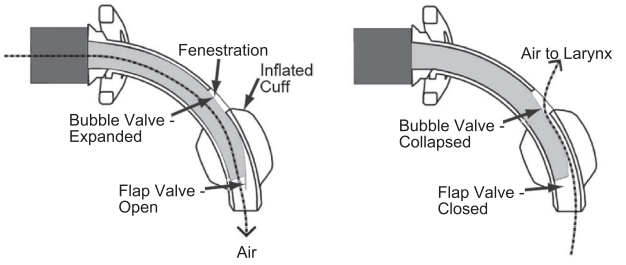

Fig. 3. Operation of the Blom Speech Cannula inside the Blom Tracheostomy Tube. Inspiratory pressure opens the flap valve and closes (expands) the bubble valve, which seals the fenestration, so all the inspiratory air goes to the lungs. As inspiration ends, the flap valve closes. Expiratory pressure collapses the bubble valve, which unblocks the fenestration and directs all the exhaled air to the upper airway to allow phonation.

als. Nine of the 10 subjects achieved audible phonation (Table 3). Subject 1's 3rd trial was discontinued, despite excellent audible phonation, due to anxiety. Subjects 4 and 10 were able to audibly phonate during 2 of the 3 trials, but required interventions (insertion of a new Speech Cannula, and repositioning) to achieve audible phonation. The number of tracheal suctionings during the trials ranged from zero to 8 in the 9 subjects who achieved audible phonation.

Two subjects experienced clinically important oxygen saturation decreases (to $< 90\%$). Subject 8 was unable to phonate during the first trial, and the second and third trials were aborted for this subject due to discomfort and intolerance of the Speech Cannula. Subject 10, who maintained an oxygen saturation of 88–93% during the 3 trials, audibly phonated with the aforementioned interventions during the second and third trials.

Fig. 4. Exhaled volume reservoir, which prevents false low-expiratory-minute-volume alarms that would occur with the Blom Speech Cannula because the air is directed through the upper airway during exhalation, instead of back to the ventilator.

All the subjects appeared to manage their own oral secretions. None of the subjects had drooling or need for oral suctioning. All the subjects were on an oral diet.

Table 4 summarizes the baseline and trial data. Note that for Subjects 1, 7, 8, and 10, the peak ventilating pressures recorded were for the mandatory ventilator driven-breaths.

Discussion

Phonation

Nine of the 10 subjects achieved sustained phonation with the Blom Speech Cannula, with the cuff fully inflated, and in all 9 of those subjects the duration of phonation and the speech intelligibility exceeded our study goals, which were for subjects to produce audible phonation during vowel prolongation and to say intelligible short phrases. All 9 subjects who were able to speak with the device produced conversational speech with their relatives and the investigators, and reported being extremely satisfied with the loudness of their speech, their vocal quality, and their overall ability to communicate. Some of the subjects were also able to converse over the telephone. Only Subject 2 had weak phonation. Her phonation was weak, breathy, and mostly of short duration, which we attribute to her diagnosis, which was C4-5 translocation with quadriplegia secondary to a motor-vehicle accident. However, she was still satisfied with her speech and was able to converse with her husband with the Blom Speech Cannula.

Unlike the 8 subjects who rapidly learned to phonate and coordinate speech with the onset of exhalation, Subject 4 took longer to initiate phonation. She initially

Table 2. Events, Changes in Physiologic and Ventilation Variables, and Interventions

Subject	Interventions	No. of Suctionings During the 3 Trials	S_{pO_2} Before the Trial %	S_{pO_2} During the Trial %	Peak Pressure Increases of > 5 cm
1	Aborted trial 3 due to patient anxiety	0	97	96	None
2	None	1	100	92–100	None
3	None	2	100	99–100	None
4	Used 2nd cannula for trials 2 and 3	8	100	100	None
5	None	7	97	95–96	None
6	None	4	95	95–96	None
7	None	4	99	98–100	None
8	Aborted trials 2 and 3 due to intolerance	Frequent	95	88	6 cm H_2O
9	None	3	98	97–98	None
10	Used 2nd cannula Repositioned the patient	5	95	88–93	7 cm H_2O in trials 2 and 3

Table 3. Phonation During Three 30-min Trials With the Blom Speech Cannula

Subject	Phonation Achieved	Trials Phonation Achieved/ Total Trials
1	Yes	2/2
2	Yes	3/3
3	Yes	3/3
4	Yes	2/3
5	Yes	3/3
6	Yes	3/3
7	Yes	3/3
8	No	0/1
9	Yes	3/3
10	Yes	2/3

had difficulty initiating speech at the onset of exhalation, but her ability to coordinate speech with expiration improved by the third trial. This initial difficulty with speech coordination did not cause any changes in her physiologic variables.

Only Subjects 1 and 8 did not complete all 3 trials. Despite successfully speaking in sentences, Subject 1 experienced anxiety and agitation during the first 2 trials, which we partially attributed to the large number of clinician observers in the room, so we aborted the third trial.

Subject 8 was the only subject who was unable to tolerate the Speech Cannula. He experienced a substantial blood pressure increase and oxygen saturation decrease. He was not ventilating well with the Speech Cannula, as indicated by changes in physiologic variables and inability to achieve phonation. He may have had an upper-airway obstruction that prevented exhalation via the upper airway, or the fenestration might have been internally blocked, preventing air flow to the nose and mouth.

Subject 10, who phonated during 2 of the 3 trials, also had changes in respiratory rate, oxygen saturation, and blood pressure, and reported some chest tightness/discomfort after 20 minutes of talking. He tolerated the Speech Cannula for a longer period during trial 3 than during the first 2 trials. We speculate that repositioning and suctioning may have contributed to that improvement. Flexible nasoendoscopic evaluation of the upper airway before and after Speech Cannula placement in Subjects 8 and 10 might have helped diagnose upper-airway obstruction or tenacious mucus buildup on the fenestration.

The peak ventilating pressure increased by > 5 cm H_2O in Subjects 8 and 10, which is consistent with our suspicion that neither of those subjects was able to fully exhale with the Speech Cannula in place (see Table 2). The Blom Speech Cannula has a narrowing inner diameter and flap valve at its distal end, which redirects the air flow. The negligible gas-flow restriction noted on inspiration during laboratory testing is attributed to that configuration, which often resulted in a small increase in peak ventilating pressure. Therefore, the high (upper) pressure limit alarm may require adjustment when a volume-control ventilation mode is used. Although the peak ventilating pressure may increase during use of the Blom Speech Cannula, Pulmodyne's laboratory testing indicated that the intrapulmonary pressure was not significantly increased (Table 5). For the other 8 subjects who achieved phonation and tolerated the Speech Cannula without substantial changes in physiologic variables, the peak ventilating pressure did not substantially increase above baseline.

Subject 4's first trial was discontinued due to air leakage between the Blom Tracheostomy Tube and the Speech Cannula. Insertion of a different Speech Cannula enabled audible phonation during trials 2 and 3 (see Table 3). Since this subject did not experience air leakage between the tracheostomy tube and the cannula during trials 2 and 3, we presumed that the air leakage had resulted from the use of a size 6 Speech Cannula within the size 8 tracheostomy tube. Unfortunately, the cannulas were discarded after the trials because the subject had an antibiotic-resistant infec-

Table 4. Baseline and Blom Tracheostomy Tube Trials Data

Subjects	Baseline: Usual Tracheostomy Tube	Non-Speech Cannula	Speech Cannula Trial 1	Speech Cannula Trial 2	Speech Cannula Trial 3
Subject 1 (ventilation mode: SIMV)					
V_T (mL)	500	500	500	500	Not performed
PS/PEEP (cm H_2O)	8/10	8/10	13/10	13/10	NR
Set/actual *f* (breaths/min)	8/23	8/21	8/20	8/20	NR
Inspiratory time (s)	2.3	2.3	2.3	2.3	NR
Peak ventilator pressure (cm H_2O)	23	25	26	26	NR
S_{pO_2} (%)	97	96	97	96	NR
Blood pressure (mm Hg)	167/66	173/78	170/80	165/80	NR
Subject 2 (ventilation mode: PS)					
V_T (mL)	NA	NA	NA	NA	NA
PS/PEEP (cm H_2O)	8/7	8/7	8/7	8/7	8/7
Set/actual *f* (breaths/min)	NA	NA	NA	NA	NA
Inspiratory time (s)	NA	NA	NA	NA	NA
Peak ventilator pressure (cm H_2O)	15	15	20	20	20
S_{pO_2} (%)	100	100	92	99	98
Blood pressure (mm Hg)	128/69	115/66	116/62	132/70	129/68
Subject 3 (ventilation mode: PS)					
V_T (mL)	NA	NA	NA	NA	NA
PS/PEEP (cm H_2O)	8/10	8/10	18/0	8/10	8/10
Set/actual *f* (breaths/min)	NA/20–22	NA/14	NA/15	NA/14	NA/15
Inspiratory time (s)	NA	NA	NA	NA	NA
Peak ventilator pressure (cm H_2O)	18	18	18	18	18
S_{pO_2} (%)	100	100	99	100	99
Blood pressure (mm Hg)	132/72	138/65	139/75	129/70	168/76
Subject 4 (ventilation mode: PS)					
V_T (mL)	NA	NA	NA	NA	NA
PS/PEEP (cm H_2O)	12/10	12/10	12/10	12/10	12/10
Set/actual *f* (breaths/min)	NA/13–16	NA/13–16	NA/16–17	NA/16–17	NA/12–16
Inspiratory time (s)	NA	NA	NA	NA	NA
Peak ventilator pressure (cm H_2O)	22	22	22	22	22
S_{pO_2} (%)	100	100	100	100	100
Blood pressure (mm Hg)	140/73	157/106	160/89	160/70	150/65
Subject 5 (ventilation mode: PS)					
V_T (mL)	NA	NA	NA	NA	NA
PS/PEEP (cm H_2O)	10/6	10/6	10/6	10/6	10/6
Set/actual *f* (breaths/min)	NA/18	NA/14	NA/14	NA/15	NA/15
Inspiratory time (s)	NA	NA	NA	NA	NA
Peak ventilator pressure (cm H_2O)	17	17	17	17	17
S_{pO_2} (%)	97	97	96	95	96
Blood pressure (mm Hg)	116/62	122/66	130/73	115/69	119/70
Subject 6 (ventilation mode: BPAP)					
V_T (mL)	NA	NA	NA	NA	NA
PS/PEEP (cm H_2O)	8/4	8/4	8/4	8/4	8/4
Set/actual *f* (breaths/min)	14/22	14/23	14/26	14/25	14/26
Inspiratory time (s)	0.5	0.5	0.5	0.5	0.5
Peak ventilator pressure (cm H_2O)	IPAP + 10	IPAP + 10	IPAP + 10	IPAP + 10	IPAP + 10
S_{pO_2} (%)	95	96	95	96	95
Blood pressure (mm Hg)	124/77	116/98	120/75	102/60	120/80
Subject 7 (ventilation mode: SIMV)					
V_T (mL)	450	450	450	450	450
PS/PEEP (cm H_2O)	15/6	15/6	15/6	15/6	15/6
Set/actual *f* (breaths/min)	12/15	12/16	12/22	12/21	12/21
Inspiratory time (s)	NA	NA	NA	NA	NA
Peak ventilator pressure (cm H_2O) (mandatory breaths)	28	23	28	24	26
S_{pO_2} (%)	99	100	98	100	100
Blood pressure (mm Hg)	105/39	110/40	120/30	150/40	130/40

(continued)

Table 4. Baseline and Blom Tracheostomy Tube Trials Data (continued)

Subjects	Baseline: Usual Tracheostomy Tube	Non-Speech Cannula	Speech Cannula Trial 1	Speech Cannula Trial 2	Speech Cannula Trial 3
Subject 8 (ventilation mode: SIMV)					
V_T (mL)	500	500	500	Not performed	Not performed
PS/PEEP (cm H_2O)	NR/8	NR/8	NR/8	NR	NR
Set/actual *f* (breaths/min)	12/24	12/22	12/35	NR	NR
Inspiratory time (s)	NA	NA	NA	NR	NR
Peak ventilator pressure (cm H_2O) (mandatory breaths)	28	29	35	NR	NR
S_{pO_2} (%)	95	94	88	NR	NR
Blood pressure (mm Hg)	148/62	149/63	190/95	NR	NR
Subject 9 (ventilation mode: PS)					
V_T (mL)	NA	NA	NA	NA	NA
PS/PEEP (cm H_2O)	NR/6	NR/6	NR/6	NR/6	NR/6
Set/actual *f* (breaths/min)	NA/21	NA/20	NA/21	NA/26	NA/20
Inspiratory time (s)	NA	NA	NA	NA	NA
Peak ventilator pressure (cm H_2O)	12	12	12	12	12
S_{pO_2} (%)	98	98	97	97	97
Blood pressure (mm Hg)	139/87	133/66	132/85	131/77	138/87
Subject 10 (ventilation mode: SIMV)					
V_T (mL)	550	550	550	550	550
PS/PEEP (cm H_2O)	NR/6	NR/6	NR/6	NR/6	NR/6
Set/actual *f* (breaths/min)	12/16	12/20	12/25	12/30	12/22
Inspiratory time (s)	NA	NA	NA	NA	NA
Peak ventilator pressure (cm H_2O) (mandatory breaths)	33	33	40	40	25
S_{pO_2} (%)	95	93	88	89	90
Blood pressure (mm Hg)	170/55	175/62	189/95	189/89	189/95

V_T = tidal volume
PS = pressure support
NA = not applicable
NR = not recorded
f = frequency (respiratory rate)
BPAP = bi-level positive airway pressure

tion, so we could not inspect the cannulas to confirm that suspicion.

Subject 4's phonation had a wet vocal quality, and we suspected she was aspirating saliva. Subject 2 was observed consuming water and thicker liquid (herb soup) while using the Speech Cannula, without clinical signs or symptoms of aspiration, nor was there evidence of soup particulates on tracheal suctioning. However, neither a full clinical nor instrumental swallowing assessment was performed with any of the subjects. Further studies to evaluate swallowing during Speech Cannula use are needed.

The goal of this study was not to compare the Blom Speech Cannula to other methods of communication traditionally used in conjunction with mechanical ventilation (leak speech, inline speaking valves, or talking tracheostomy tubes). Rather, the purpose was to investigate the safety and efficacy of a new device, the Blom Tracheostomy Tube and Speech Cannula, which is the only available product that entirely redirects exhaled air into the upper airway while the cuff remains fully inflated. However, because Subject 2 thoroughly enjoyed the opportunity to talk with the Blom Speech Cannula, and her physicians felt she was going to require long-term ventilator support, we did attempt traditional leak speech with this subject to determine if she could tolerate a small cuff leak for verbal communication. In less than 10 min with a small cuff leak she reported shortness of breath, so her cuff was re-inflated. For this subject the Blom Speech Cannula appeared to be an easier and more effective alternative for achieving phonation for longer than she could achieve with cuff leak.

Prior to his participation in this study, Subject 6's physicians noted that he was depressed and frustrated by his dependence on mechanical ventilation and inability to verbally communicate. To help alleviate his depression, his attending physician used a BPAP ventilation mode to allow him to speak for brief periods with a small cuff leak. He was using a Respironics Esprit ventilator in the "NIV" (noninvasive ventilation) mode, which is typically used for noninvasive ventilation, but was used with this (tracheos-

Table 5. Peak Pressures With the Blom Standard, Non-speech Cannula and the Blom Speech Cannula*

	Ventilator Peak Pressure (cm H_2O)		Intrapulmonary Peak Pressure (cm H_2O)	
Flow (L/min)	Speech Cannula	Non-speech Cannula	Speech Cannula	Non-speech Cannula
30	30	30	25	28
40	34	32	26	28
50	38	35	27	28

* Ventilator settings: tidal volume 800 mL, respiratory rate 12 breaths/min, square wave flow pattern. All tubes 6.0 mm inner diameter. Data provided by Pulmodyne, Indianapolis, Indiana.

tomized) patient because this mode allows more leak without alarming than do traditional ventilation modes. Though he was only able to tolerate cuff-leak speech for a few minutes, he tolerated the Blom Speech Cannula throughout all three 30-min trials, and talked to his relatives on the telephone during each trial. He reported being very satisfied with his speaking ability, vocal quality, and the device in general. Because of time restraints, comparison of cuff-leak speech and the Blom Speech Cannula was not further explored in this study, so we do not know if the other subjects who successfully phonated with the Blom Speech Cannula could have used cuff-leak speech, a talking tracheostomy tube, or an inline speaking valve. However, comparing tolerance of the available phonation options in individuals requiring ventilator support would be an excellent topic for future research.

Limitations

We did not record inspiratory time or inspiratory-expiratory ratio in all the subjects. The inspiratory and expiratory times may be important to monitor and/or adjust in future studies, because a longer expiratory time may improve the duration of phonation and prevent air trapping. Additionally, Subject 2's respiratory rate was not recorded. In future studies, as well as in clinical use of the Blom Speech Cannula, we recommend recording all physiologic variables and monitoring closely for changes.

Conclusions

This preliminary study with the Blom Tracheostomy Tube and Speech Cannula demonstrated successful phonation and ventilation in 9 of the 10 subjects. All 9 subjects who phonated reported great satisfaction with their speech quality. We supervised the subjects continuously during the trials and concluded that patient safety was never compromised.

Suctioning through the flap valve of the Speech Cannula did not interfere with the function of the valve/cannula. Note that subjects with thick or copious secretions are not candidates for the Blom Speech Cannula. A patient with an enlarged tracheostoma that cannot adequately seal around the tracheostomy tube should also not use the Blom Speech Cannula, since this will result in air leak.

Extensive laboratory work was done by the manufacturer, Pulmodyne, throughout the development of the Speech Cannula, as well as upon completion of the design, to ensure the structural integrity and function of the valves and smooth insertion of the cannula into the tracheostomy tube. Though a new Speech Cannula was used for each 30-min trial during this study, the current directions for use indicate that the Blom Speech Cannula is a 60-day reusable device, which should be cleaned with sterile water or saline after each use. Immediately after inserting the Speech Cannula the clinician must ensure that the subject is able to exhale via the upper airway, by eliciting speech, feeling for air flow from the patient's nose and mouth, and/or auscultating the upper airway. If upper-airway flow is insufficient or if physiologic or ventilator variables reach unsafe levels, the Speech Cannula should immediately be removed and replaced with the standard (non-speech) cannula.

In addition, the patient's oxygen saturation should be closely monitored during Speech Cannula placement, and the Speech Cannula should be removed immediately if oxygen saturation decreases substantially.

We recommend flexible nasoendoscopy prior to placing the Blom Speech Cannula, to confirm upper-airway patency, intact bilateral vocal-fold abduction/adduction, and that the fenestration is not in contact with the tracheal mucosa. Nasoendoscopy also allows the practitioner to inspect for pooled pharyngeal secretions and to assess how effectively the patient is managing saliva, whether saliva aspiration is occurring, and if pharyngeal suctioning is needed. Future studies will determine the implications of these findings on the successful use of the Speech Cannula.

Use of the Blom Speech Cannula must be ordered by a physician, and initial trials will be most beneficial when jointly conducted by the treating respiratory therapist and speech language pathologist. The respiratory therapist will be integral in selecting the appropriate placement of the Exhaled Volume Reservoir, adjusting alarm thresholds, and increasing peak flow and/or reducing inspiratory time to extend the expiratory phase to maximize phonation duration without air trapping. The role of the speech language pathologist will include assessing for upper-airway air flow, assisting the patient in initiating phonation, teaching the patient to maximize speech duration and intensity, and completing swallowing evaluations.

In summary, when continuously monitored by trained clinicians, the Blom Speech Cannula appears to be both

safe and effective in facilitating phonation in tracheostomized ventilator-dependent individuals, while maintaining full cuff inflation. Patients who are known or suspected to be aspirating saliva, or are unable to tolerate cuff deflation may benefit from the Blom Speech Cannula. The Blom Speech Cannula may also help reduce depression, fear, and anxiety associated with inability to communicate. A multicenter investigation of speech with the Blom Tracheostomy Tube and Speech Cannula is underway in the United States.

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