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Research Note

# Experimental Assessment and Future Applications of the Shikani Tracheostomy Speaking Valve

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**Purpose:** Tracheostomy speaking valve use may increase airflow resistance and work of breathing. It remains unclear which valve offers the best performance characteristics. We compared the performance characteristics of the Shikani speaking valve (SSV; unidirectional-flow ball valve) with those of the Passy-Muir valve (PMV; bias-closed flapper valve).
**Method:** Airflow resistance was measured for both the SSV and the PMV at 8 flow amplitudes and in 3 orientations (–15°, 0°, +20°) in the bias-open and bias-closed configurations.
**Results:** Significantly lower airflow resistance was observed for the SSV (bias open) compared with the PMV at –15° ($p < .001$), 0° ($p < .001$), and +20° ($p = .006$) from the horizon. No significant difference was observed between the PMV and the SSV (bias-closed) configuration at any of the tested angles. A nonsignificant trend toward decreased airflow resistance was observed between the SSV bias-open and bias-closed configurations at each of the angles tested.
**Conclusions:** The SSV demonstrated lower airflow resistance compared with the PMV across 8 flow amplitudes in the bias-open configuration at –15°, 0°, and +20° from the horizon. Further investigation is needed to determine the clinical impact of these findings on patient comfort, work of breathing, phonation, and airway protection during swallowing.

Mechanical ventilation is an essential tool in the management of patients with acute and chronic respiratory failure (Bach, Ishikawa, & Kim, 1997; DeVivo & Ivie, 1995). Many patients will require tracheostomy to facilitate prolonged ventilator support for reasons including progression of their underlying illness and management of acute and chronic comorbidities (Heffner, 1989). Placement of a tracheostomy tube reduces airway resistance, extrathoracic dead space, and work of breathing by an estimated 30% compared with endotracheal intubation (Diehl, El Atrous, Touchard, Lemaire, & Brochard, 1999; Moscovici da Cruz et al., 2002; Prigent et al., 2006). However, the loss of verbal communication as well as negative effects on swallowing following tracheostomy placement may negatively affect the patient's medical care, social interactions, and psychiatric well-being (Dettelbach, 1995; Elpern, Borkgren Okonek, Bacon, Gerstung, & Skrzynski, 2000; Prigent et al., 2012; Shikani, French, & Siebens, 2000; Suiter, 2003).

For appropriate patients, the use of a tracheostomy speaking valve may facilitate phonation and increase positive end-expiratory pressure. High expiratory resistance (and pressure) is the major reason for increased work of breathing and poor tolerance when speaking valves are used (Johnson, Campbell, & Rabkin, 2009). One-way valves are ubiquitously used to lower the likelihood of adverse pulmonary outcomes associated with dysphagia caused by the effect of tracheostomy on airway pressures. An expiratory occlusive valve can reduce, though not eliminate, occurrences of aspiration by restoring the passive expiration toward the upper airway after swallowing (Elpern et al., 2000; Ohmae et al., 2006; Prigent et al., 2012). Speaking valves function by closing during exhalation to direct flow through the vocal cords, thus restoring the ability to phonate. A number of commercially available speaking valves have been described in the literature, including the Passy-Muir valve (PMV; Passy-Muir, Irvine, CA), the Shiley Phonate valve (Mallinckrodt Pharmaceuticals, Chesterfield, United Kingdom), and the Montgomery tracheostomy speaking

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valve (Boston Medical Products, Westborough, MA). Each of the aforementioned valves is a flapper valve (Prigent et al., 2006). The PMV is bias closed (i.e., closed during rest and exhalation and open only upon inspiration), whereas the Shiley Phonate and Montgomery valves are bias open (i.e., open during rest and inhalation and closed only upon expiration; Passy, Baydur, Prentice, & Darnell-Neal, 1993).

In contrast to speaking valves that are based on flapper valve technology, the Shikani speaking valve (SSV; Shikani Medical, The Airway Company LLC, Lutherville, MD) is a unidirectional-flow valve that utilizes a ball rather than a flap to seal the speaking valve port and was designed to fit all standard plastic tracheostomy tubes with a 15-mm inner cannula (Shikani et al., 2000). The updated version introduced in 2013 (see Figure 1) features a polymer cage with a 2.5° ramp and a ball-stop mechanism comprising parallel vertical bars. The position of the ball within the body of the speaking valve varies with the patient's breathing pattern and posture. During inhalation the ball rolls posteriorly into the valve seat, and during exhalation it rolls forward toward the valve frontal port. The patient can also cause the ball to move toward the frontal port by bending forward and can cause it to sit posteriorly in the valve seat by leaning backward. In addition, the SSV can be attached to the inner cannula of the tracheotomy tube in two possible positions. When the port is in the 12 o'clock (valve up) position, the valve assumes the bias-open configuration (see Figure 2). When the port is in the 6 o'clock (valve down) position, the valve assumes a bias-closed configuration, which causes the ball to roll forward down the ramp toward the front port (see Figure 3). Thus, patients may be able to augment respiration and phonation by simply modifying neck position or valve configuration.

**Figure 1.** (A) The framework and design of the Shikani speaking valve. (B) The Shikani speaking valve port is eccentric (slightly off center) in relation to the valve body.

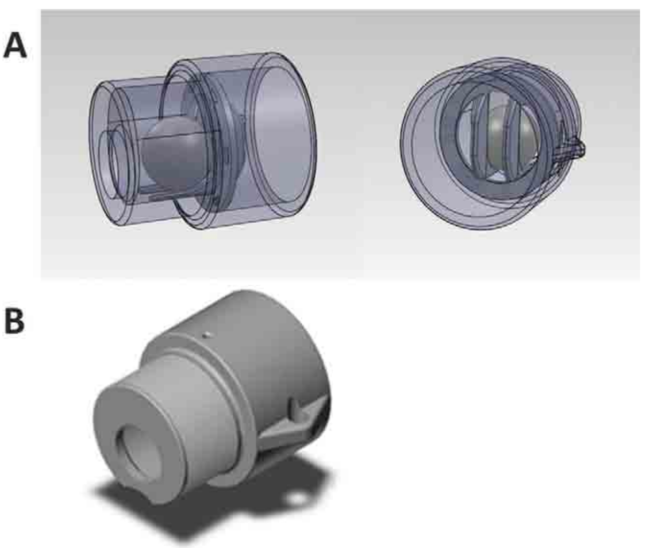
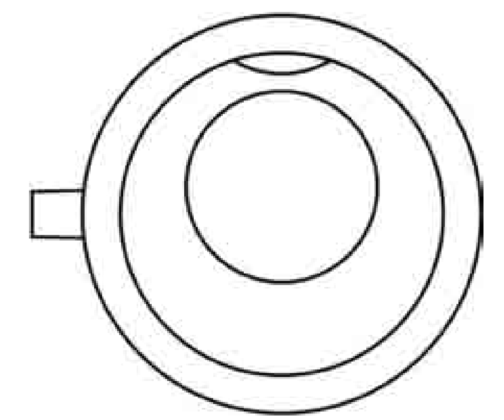


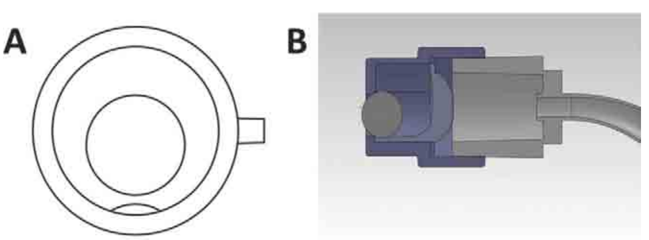

**Figure 2.** The Shikani speaking valve port at the 12 o'clock position. The small, half-moon–shaped notch on the front is positioned at 12 o'clock (the valve-up or bias-open configuration).



The use of any tracheostomy speaking valve may increase resistance to airflow and can potentially increase work of breathing due to an increase in expiratory resistance. The resistance of speaking valves varies, with one study finding a range from 1.3 to 5.9 cm $H_2O \cdot L^{-1} \cdot s^{-1}$ (Prigent et al., 2006). At a flow of 0.5 L/s, pressures across the valves ranged from −0.95 to −3.59 (−1.47 for Shiley Phonate; −2.32 for Passy-Muir). An inverse relationship was noted between the valve pressure and dyspnea as measured by the Borg Dyspnea Scale (Borg, 1982), with a large increase in Borg scale values (from 1.7 to 4.8) using the valve with a pressure of −3.59. This supports a recent recommendation to avoid tracheostomy capping if the inspiratory pressure is more negative than −3 (Johnson et al., 2009).

The clinical implications of this remain unclear. Although a number of flapper valves have been compared in this regard, the performance characteristics of the Shikani ball valve compared with the Passy-Muir bias-closed flapper valve have not been assessed (Fornataro-Clerici & Zajac, 1993; Prigent et al., 2006; Zajac, Fornataro-Clerici, & Roop, 1999). As a new technology, controlled laboratory investigation is necessary to establish baseline flow characteristics of the SSV and provide pilot data to justify prospective clinical investigation. The aim of this study was to examine the

**Figure 3.** The Shikani speaking valve port at the 6 o'clock position. The small, half-moon–shaped notch on the front is positioned at 6 o'clock (the valve-down or bias-closed configuration).



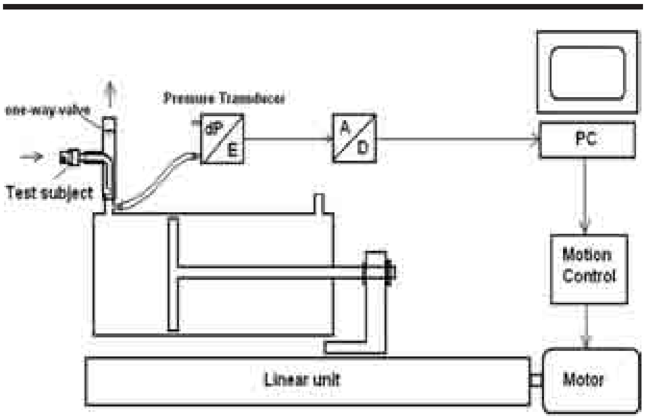
airflow characteristics of the SSV in comparison with the PMV in a controlled laboratory environment to determine whether a significant difference in airflow resistance exists between products. The data from this pilot study will serve as the platform and justification for subsequent prospective clinical investigation in patients who have been educated on proper use of both tracheostomy speaking valve products, thereby allowing for internal comparison.

## Materials and Method

Speaking valves were connected to a differential transducer (Kal 84; Halstrup-Walcher, Kirchzarten, Germany) and to a pneumotachometer (TSI 4040E; TSI, Shoreview, MN) to allow for the measurement of air pressure and flow (see Figure 4). Valves were mounted on a cannula integrated with a T-piece. One end of the T-piece was connected to the outlet of the piston pump, and the other end was equipped with a one-way valve. The calibrated pneumotachometer device was connected in sequence with the pressure source. In this configuration, the inspiratory flow may only pass through the speaking valve. Pressure was measured at the distal end of the cannula, which was coupled to a positive and negative pressure source. By varying the voltage to the device through a variable transformer, one may vary the positive or negative pressures generated by the blower. The pneumotachometer was set to generate a tidal volume of 0.5 L/cycle at a rate of 20 cycles/min with a square-wave flow curve. The experiment was conducted at varying airflow rates, with a flow range from 0.00 to 0.36 L/s, corresponding to rates experienced during normal breathing and/or light activity by patients with conventional flapper-valve tracheostomy speaking valves (Bard, Slavit, McCaffrey, & Lipton, 1992; Holmberg, Hillman, & Perkell, 1988).

A differential pressure transducer was used to measure the change in pressure ($\Delta P$) with one port connected to the piston-pump outlet and the other open to ambient air. The flow amplitude was increased in stepwise increments of 50 ml/s. The technique was repeated for a total of five measurements at each level of specified flow amplitude. The average value of each point on the resulting pressure curve, which corresponds to the last third of the flow curve, was taken for each step phase. The mean of these calculated values was then the resulting flow-dependent $\Delta P$ at the respective flow step. To compensate for $\Delta P$ across the system, pressure change was measured at all flow rates without the test speaking valve connected, and these values were subtracted from the $\Delta P$ measured with the valve connected. The corrected pressures were used to generate the $\Delta P$–flow curve.

**Figure 4.** Schematic of the pneumotachometer.




All results are expressed as mean ± standard deviation (He et al., 2013). Differences between the two valves were tested using multifactorial analysis of variance for repeated measurements. When the analysis of variance reached a $p$ value less than .05 ($F$ test), pairwise comparisons were performed using the least squares means for resistance with 95% confidence intervals. A $p$ value less than .05 was considered statistically significant.

## Results

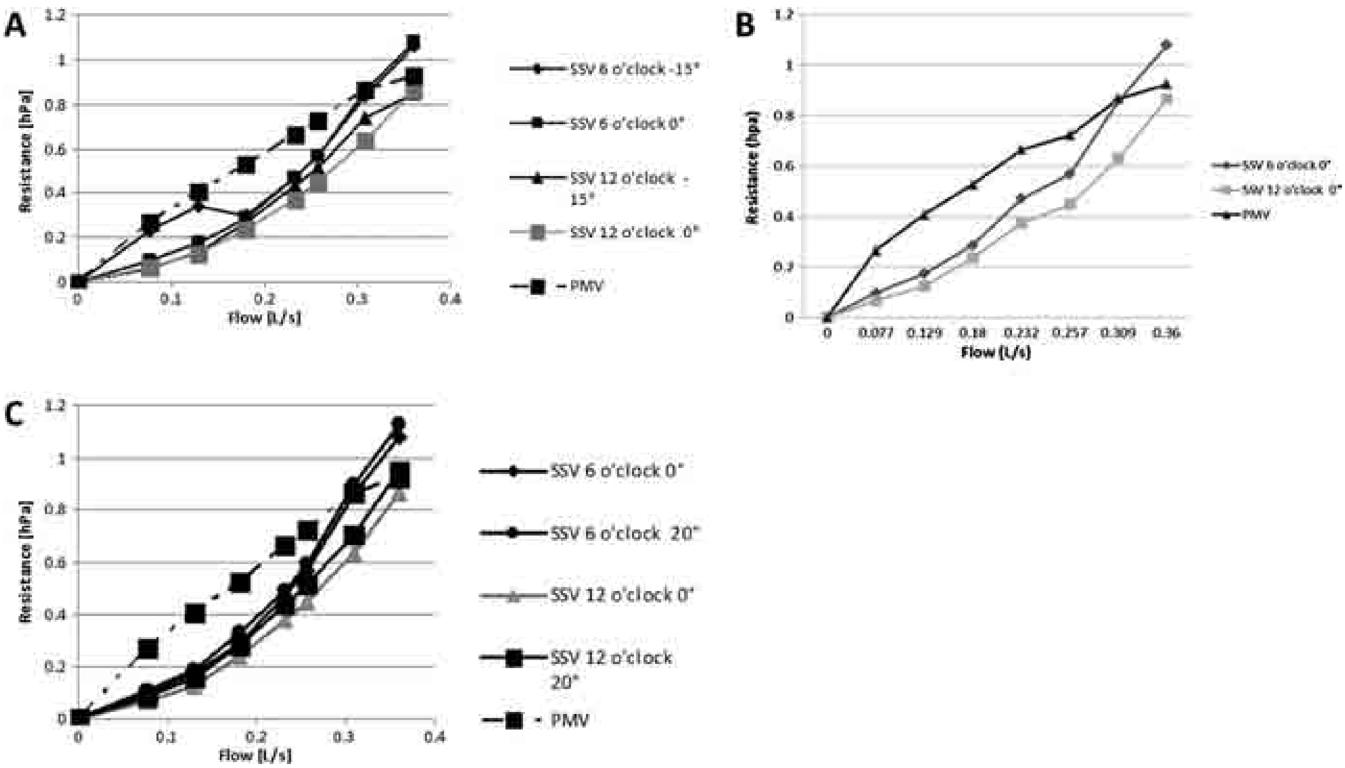
Significantly lower expiratory airflow resistance was observed between the SSV (bias open) and the PMV at −15° ($p < .001$), 0° ($p < .001$), and +20° ($p = .006$) from horizontal (see Figure 5). No significant difference was observed between the PMV and the SSV (bias closed) at any of the three angles tested. Although a trend for decreased airflow resistance existed between the SSV bias-open and bias-closed configurations at each of the angles tested, results did not reach statistical significance. In addition, significantly lower inspiratory airflow resistance was observed between the SSV (bias closed) and PMV at various flow resistances tested while the valves were at 0° from horizontal ($p < .01$; see Figure 6). Inspiratory airflow resistance was not tested at −15° and +20° from horizontal.

## Discussion

The ability to speak greatly enhances the quality of life for many patients with a tracheostomy, and a number of devices are commercially available for use in either mechanically ventilated or spontaneously breathing patients. Although tracheostomy placement decreases airways resistance and extrathoracic dead space, the application of a speaking valve may increase inspiratory airflow resistance and work of breathing. Thus, the lower the airflow resistance generated by a tracheostomy speaking valve, the less potential there is for negatively affecting work of breathing. In addition, tracheostomy speaking valves can potentially improve quality of life by improving swallowing and decreasing aspiration (Elpern et al., 2000; Prigent et al., 2012).

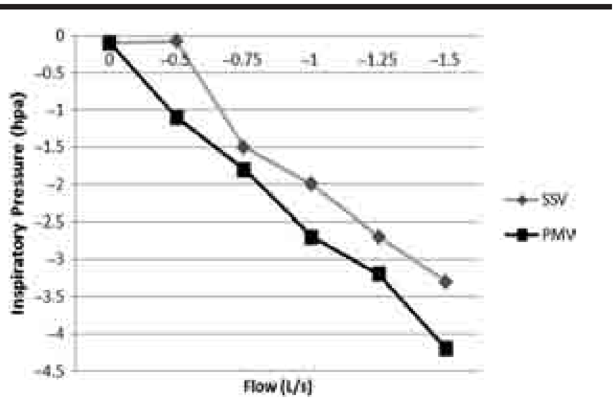
Upper airway resistance varies according to age and gender but is estimated as $3.93 \pm 0.56$ cm $H_2O \cdot L^{-1} \cdot s^{-1}$ in awake adults with normal respiratory function (Hudgel, Martin, Johnson, & Hill, 1984; Vig & Zajac, 1993). In keeping with prior reports, both tested valves in this experiment presented resistances that were below this estimation of upper

Figure 5. Expiratory airflow resistance curves for the Shikani speaking valve (SSV) and the Passy-Muir valve (PMV). Significantly lower airflow resistance was observed between the SSV (bias open) and the PMV at (A) −15°, (B) 0°, and (C) +20° from horizontal. No significant difference was observed between the PMV and the SSV (bias closed) at any of the three angles tested.




airway resistance. In the described experiment, significantly lower expiratory airflow resistance was observed while the SSV was in the bias-open (12 o'clock) configuration compared with the PMV (see Figure 5). In addition, significantly lower inspiratory airflow resistance was observed between the SSV (bias closed) and the PMV at 0° from horizontal (see Figure 6). These findings may be explained by the SSV's unique polymer cage design that allows a bias-open or a bias-closed position. The bias-open position allows the exhaled air to escape through the proximal opening with quiet respiration, or, alternatively, the air may be redirected toward the larynx with a slight exhalation, hence achieving vocalization. The bias-closed position ("positive closure" feature) allows the ball to roll forward along a 2.5° ramp toward the frontal opening of the valve, thus closing and maintaining valve closure until sufficient inhalation flow, or negative pressure, is applied. The negative pressure pulls the ball back posteriorly for a brief period until the end of inspiration, when the ball readily returns to the closed position without air leak. The SSV can hence be used in the valve-up (bias-open) or valve-down (bias-open) positions depending on the position of the ball—a feature that theoretically allows the patient a better degree of control over airflow. Furthermore, the ramps inside the valve chamber not only act as a stop mechanism but also function as a dynamic guide that directs the ball to move with less resistance toward the front or the back of the chamber depending on the posture of the patient. This contrasts with the PMV, in which the flap is closed at the initiation of inspiration unless enough flow is generated to overcome both the inertia of its mass and its spring tension.

Figure 6. Inspiratory pressure changes for flow-dependent tracheostomy speaking valves. SSV = Shikani speaking valve; PMV = Passy-Muir valve.




In a study by Zajac et al. (1999), the aerodynamic properties of six tracheostomy speaking valves were measured with and without an inner cannula. Resistance measurements were made at four flow rates (150, 250, 350, and 450 ml/s) with positive pressure at the valve's input port (Zajac et al., 1999). All valves exhibited relatively low resistance compared with the typical nasal resistance reported for adults. However, in contrast to our results, significant differences among the tested tracheostomy speaking valves were established only at the lowest flow rate. Moreover, Zajac et al. (1999) demonstrated a nonlinear relationship between the pressure and the flow rate, which may be attributed to the limited number of data points tested. This contrasts to the current study, which analyzed eight different flow amplitudes.

Unlike prior studies, this investigation also evaluated the relation between the SSV orientation and airflow resistance through the tracheostomy tube. Tilting the SSV in a backward direction (+20° above horizontal) would correspond clinically to having a patient in a normal sitting position. In this configuration, the ball will rest posteriorly within the valve cylinder against the stop. As such, lower resistance is met during the inspiratory effort. However, theoretically higher flow may be necessary to overcome the effect of gravity as well as that of the mass of the ball in order to seal the SSV port. On the other hand, tilting the valve forward (−15° below horizontal) to simulate a patient bending forward would result in the ball resting against the SSV's port. As such, a slightly higher flow may be required upon inspiration to raise the ball against gravity as well as move it to the posterior stop. It is interesting to note that in our experiment we observed lower flow resistances between a bias-open SSV (12 o'clock) and the PMV at each of the angles tested.

The clinical significance of such findings remains unclear. However, in a study of 10 patients, significant improvement in speech naturalness was reported with the SSV compared with the PMV and Shiley Phonate (Shikani & Dietrich-Burns, 2012). It was hypothesized that these findings were attributable to the patients' adaptation, either conscious or subconscious, by learning to intuitively control the ball action through head and body movements and/or variations in respiration.

## Conclusions

The SSV, a ball speaking valve, demonstrated lower expiratory airflow resistance compared with the PMV across eight flow amplitudes in the bias-open configuration at −15°, 0°, and +20° from horizontal. Further prospective investigation by independent researchers is needed for validation of these findings. Such investigation should be a sufficiently powered, controlled clinical trial to assess whether the lower airflow resistance is reproducible and whether it translates into clinical differences in patient comfort, work of breathing, swallowing, and phonation.

## Limitations

Our study compared the airflow characteristics and resistance patterns of the SSV with those of the PMV because the latter is the most widely prescribed and studied flapper tracheostomy speaking valve. Nevertheless, several other studies demonstrated similarities between the aerodynamics of the PMV and those of other flapper valves (Fornataro-Clerici & Zajac, 1993; Prigent et al., 2006; Zajac et al., 1999).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