DRUG/DEVICE CAPSULES

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New unidirectional airflow ball tracheostomy speaking valve

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Tracheostomy is frequently performed to relieve obstruction of airflow through the larynx and upper trachea. One of its main side effects is loss of essential functions, including warming and filtering of air, coughing, smelling, tasting, swallowing, and more devastatingly speaking. Voice production requires vibration of the vocal cords by a stream of air that passes through the larynx during exhalation. When a tracheotomy is present, exhaled air follows the path of least resistance and goes through the tube, reducing the vibratory movement of the vocal cords and hence limiting perceptual speech. This creates a psychological hardship because communication is critical to patients' overall medical care and social interactions.[1,2] This problem can be particularly disruptive in children because, as has been demonstrated previously,[3,4] tracheotomy can affect the development of normal language skills.

To redirect the air through the vocal cords, the patient may use a finger to occlude the tracheostomy tube. However, finger occlusion has several limitations: it requires manual dexterity that many patients lack, it requires coordination of phonation with breathing, and it is unsanitary. The use of a tracheostomy speaking valve enables tracheostomy patients to speak without having to occlude the tracheostomy tube with the finger. A variety of speaking valves have been described in the literature and are on the market. These include the Passy-Muir valve (Passy-Muir Inc), Shiley Phonate valve (Mallinckrodt Medical), Montgomery speaking valve (Boston Medical Products), and Kistner speaking valve (Pilling-Rusch Corp), which are all flapper valves, and the Olympic speaking valve (Olympic Medical Corp), which is a disk valve. Passy-Muir is a bias-closed valve (ie, closed at all times except on inspiration), and the rest are bias-open valves (ie, open at all times except on expiration).

Fornataro-Clerici and Zajac[5] investigated the resistance of 4 different valves (Kistner, Montgomery, Olympic, and Passy-Muir) and found that the Kistner valve had significantly higher resistance to airflow than the other 3 valves. Moreover, significantly higher pressures were required to open the Passy-Muir valve than to open the Olympic and Montgomery valves. The authors hypothesized that the resistance inherent to the valves may have an effect on patients' tolerance of the valves, thereby affecting both patient and valve selection.

We present a different type of speaking valve, which is a unidirectional flow ball valve. Because of the flexibility in the design of its coupling mechanism to a given cannula set, it has a lower resistance and is more easily hidden under clothing than either flapper or disk valves.

METHODS AND MATERIAL

Valve Design and Technique of Attachment to Tracheostomy Tube

Figure 1 shows a cross section of our valve connected to a No. 6 Jackson metal inner cannula. Figure 2 shows the operational sequence of the ball valve. The patient is assumed to be standing or sitting upright, and the valve is in the 6 o'clock position. In the resting state, the ball lies on the wall of the air chamber. On inspiration, the ball moves toward the opening of the cannula but is stopped by a piece of wire, which runs across the diameter of the valve body. Air enters the cannula as with the normal operation of a tracheostomy tube. On expiration, the ball rolls into the valve seat, blocking airflow through the cannula and forcing the air to go through the larynx as with normal expiration. The port of the valve is made eccentric with relation to the valve body. The center of the port is essentially the same distance from the inside wall of the valve as the radius of the ball (allowing for ball tolerance in both diameter and sphericity). This way, the ball simply rolls into the valve seat during expiration. If the port were con-

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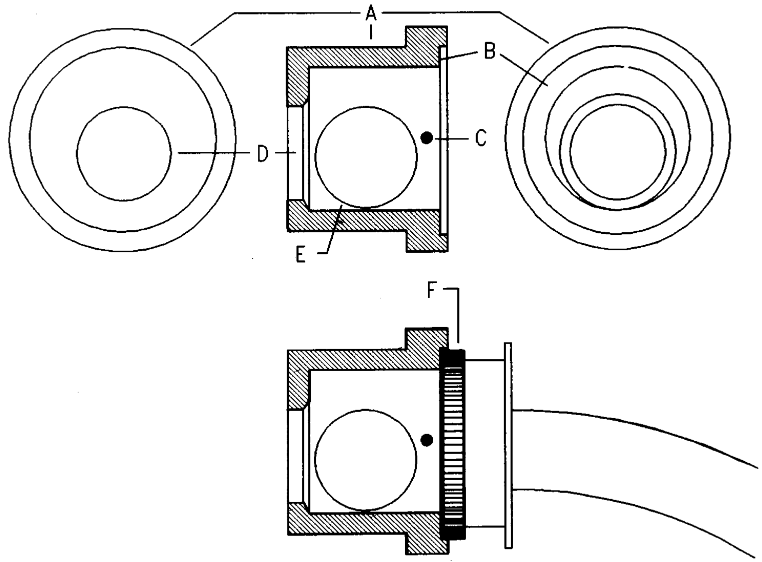

Fig 1. Cross section of ball valve connected to a No. 6 Jackson metal inner cannula. *A,* Valve body; *B,* recess into which the cannula flange fits; *C,* ball stop, which prevents the ball from entering the cannula; *D,* combination input port and valve seat (note that this is not concentric with the axis of the valve body); *E,* ball; *F,* flange on a Jackson low-profile metal inner cannula.

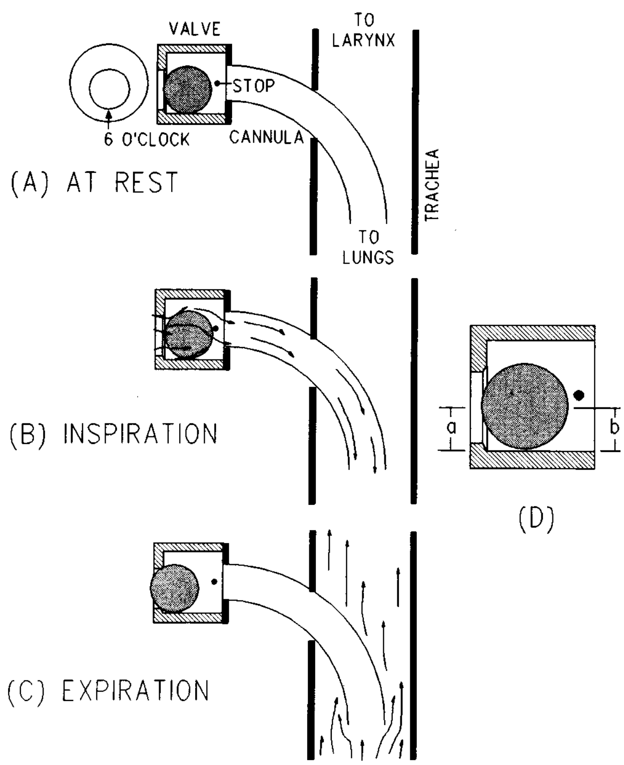

Fig 2. Operational sequence of the ball valve. **A,** Valve is in the 6 o'clock position. In the resting state, the ball lies on the wall of the air chamber. **B,** On inspiration, the ball moves toward the opening of the cannula but is stopped by a piece of wire *(STOP)* that runs across the diameter of the valve body. Air enters the cannula as with the normal operation of a tracheostomy tube. **C,** On expiration, the ball rolls into the valve seat, blocking airflow through the cannula and forcing the air to go through the larynx as with normal expiration. **D,** Center of the port *(a)* is essentially the same distance from the inside wall of the valve as the radius of the ball *(b)* (allowing for ball tolerance in both diameter and sphericity).

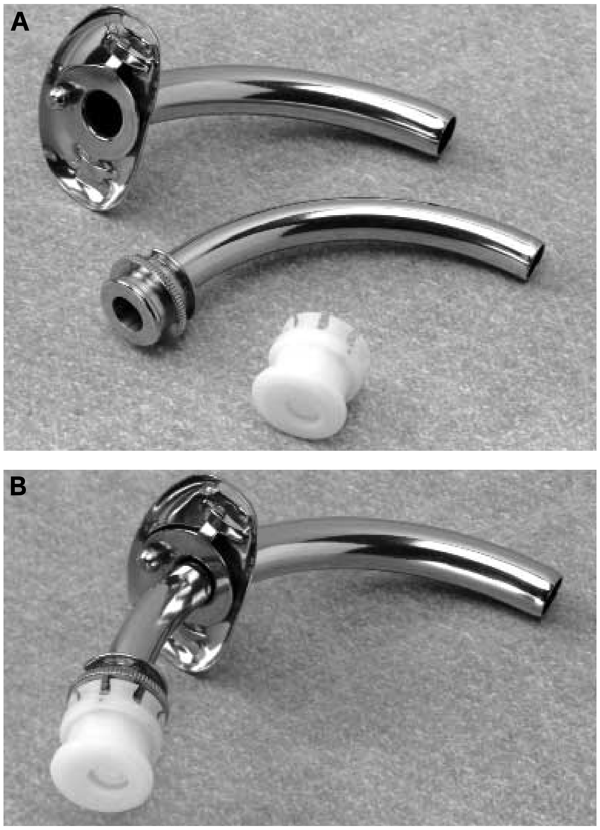

Fig 3. Actual ball valve next to **(A)** and coupled to **(B)** the inner cannula of a No. 6 Jackson metal tracheotomy tube (clip-on mechanism of attachment).

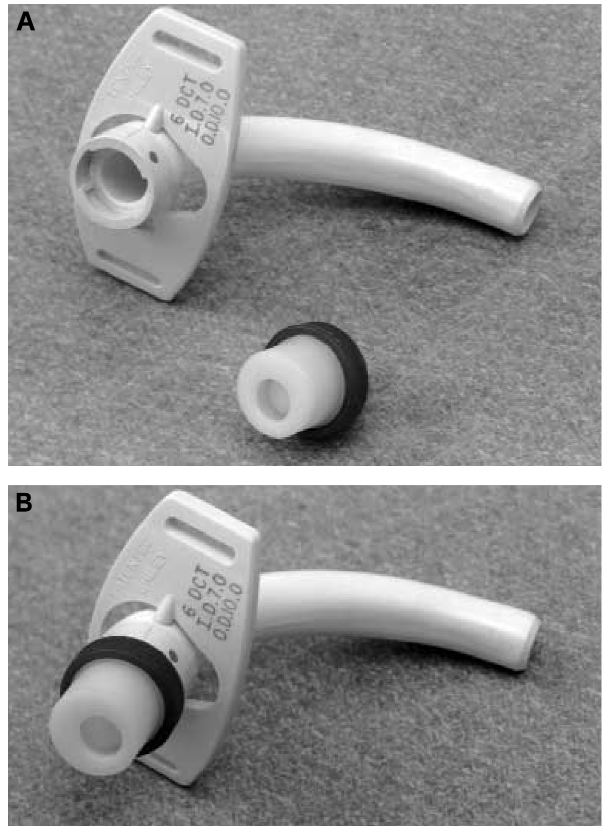

Fig 4. Actual ball valve next to **(A)** and coupled to **(B)** a No. 6 Shiley tracheotomy tube (twist-lock mechanism of attachment).

centric, a higher pressure would be required to lift the ball into its seat, with consequent delay, which could cause truncation or distortion of leading syllables during speech. With the eccentric configuration, the pressure required for valve closure is less, and closure is almost instantaneous, which is particularly important in patients with very low tidal volumes and vital capacities.

What makes this valve unique is that its compact design allows it to be coupled to the low-profile versions of all of the most popular commercially available tracheotomy cannulas, either metal or plastic, and allows it to be easily concealed under clothing. With some cannula sets it can be configured to actually replace the inner cannula,[6] which results in significantly lower resistance. The valve comes in 2 forms: a clip-on type that attaches by pressure to the inner cannula of the metal CL Jackson tracheostomy tube (Fig 3), and a twist-lock type that attaches by twisting directly to the plastic tracheostomy tube itself (Fig 4). The valve, which is manufactured by Pilling Weck Surgical, has also recently been made available as a clip-on attachment to the disposable 15-mm inner cannulas of the plastic tracheostomy tubes.

All of the other commercial valves currently on the market are designed to fit only onto the standard 15-mm fitting of the inner cannula of plastic tracheostomy tubes. The disadvantage of this mounting configuration is that it is a force-fit coupling, which makes the valve more difficult to remove from the cannula, especially if too much force was used initially for coupling. On the other hand, if insufficient force is applied and the patient coughs, the valve could pop off and literally fly across the room. The twist-lock mechanism of attachment of the ball valve eliminates this problem and makes the coupling more user-friendly, which is particularly important in patients with poor dexterity. In addition, it has better airflow characteristics than the other commercially available speaking valves (Shiley and Passy-Muir).

Testing Procedures

To be able to compare the qualities of the various valves, the physician must have a basic knowledge of the behavior of air in a tracheostomy cannula alone. In its simplest form a cannula is a straight, cylindrical tube of metal or plastic through which the patient breathes. It keeps the tracheostomy stoma open. The airflow through the tube varies with the square of the negative pressure generated by the patient. When

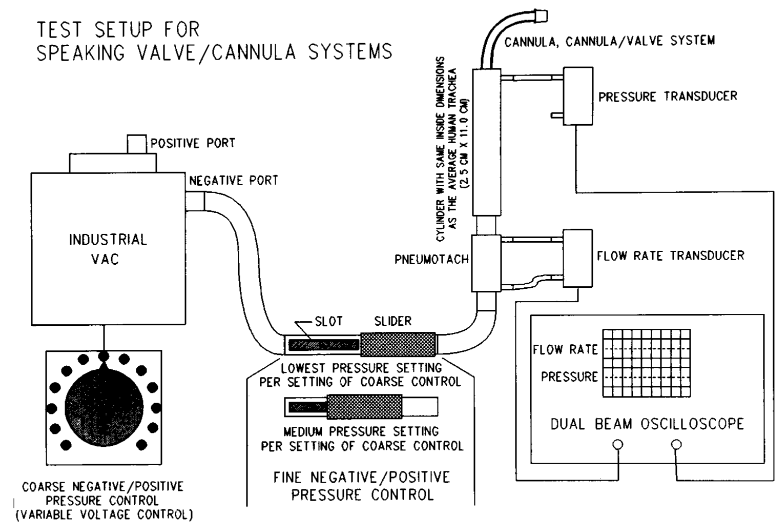

Fig 5. Diagram of pneumotachometer used to measure the inspiratory and expiratory flow characteristics of the speaking valves.

a valve is fastened to a cannula, the combination must be treated as a system. Measuring the flow characteristics of a given valve as an entity is in itself meaningless. The characteristics of the entire system consisting of a valve and a cannula must be obtained. The same size and style of cannula (a No. 6 Shiley plastic tracheotomy set) was used for each valve tested.

Fornataro-Clerici and Zajac[5] have measured the characteristics of several commercial valves both without a cannula and mounted on a cannula with an inside diameter of 8.5 mm. The measurements were made at 4 flow rates (150, 250, 350, and 450 mL/second) with positive pressure at the valve's input port. Their results showed that there was a nonlinear relationship between the pressure and the flow rate, but the limited number of data points brings to question the validity of their nonlinear relationship. We believe that a pressure-flow rate relationship is more precisely defined with at least 10 or, even better, 20 data points, which is the number of points we determined when testing our valve and comparing it with the other valves. The flow rate range was from 0 to 1 L per second. When the points were plotted, it was easy to see the difference between the various valve-cannula systems at all flow rates within that range.

The means of measuring the inspiratory and expiratory flow characteristics of a given valve-cannula assembly are shown in Fig 5. Pressure was measured at the distal end of the cannula, which was coupled to a positive or negative pressure. Flow was measured with a calibrated pneumotachometer, which was in series with the pressure source. The heart of the setup was an industrial vacuum machine, chosen because it was a simple and inexpensive source of both negative and positive pressure. Varying the voltage to the motor varied its speed and therefore the pressure generated by the blower. We used a variable transformer to control the speed. Fine pressure control was obtained through a slot in a rigid section of the supply line, permitting leakage of either positive or negative flow. The slider controlled the leakage from maximum (slot completely open) to 0 (slot completely closed)—the wider the opening, the lower the pressure.

The pneumotachometer was an A. Fleisch No. 1.962, the flow rate transducer was a Micro Switch No. 163PC01D36 with an appropriate interface, the pressure transducer was a Micro Switch No. 142PC01D with an appropriate interface, and the oscilloscope was a Beckman Industrial No. 9020. The cylinder, which had the same inside dimensions as the average human trachea (2.5 × 11 cm), was made of clear PVC (polyvinylchloride) tubing.

RESULTS

All of the major manufacturers have limited their coupling options to a one size fits all approach (ie, they all fit on the 15-mm fitting that is available on the inner cannula of most commercial cannula sets). Our design approach enables the valve to be coupled to the low-profile inner cannula of any cannula set, or even to replace the inner cannula altogether and attach directly to the outer cannula.[6] This theoretically should allow the valve-cannula system to be optimized for lower air resistance. Figure 6 confirms the correctness of this assumption and illustrates graphically the advantage of having this flexibility of design. In Fig 6 the ball valve's forward flow characteristics are compared with those of 2 representative commercial valves and with a No. 6 inner cannula alone and a No. 6 outer cannula alone. Shiley represents the flapper valve biased open. Passy-Muir represents the flapper valve biased closed. All of the commercial valves were mounted, as directed by their manufacturer, on the 15-mm connector of a Shiley No. 6 plastic inner cannula. The cannula is a cylindrical tube approximately 8.9 cm long with an inner diameter of approximately 0.714 cm (cross-sectional area [CSA] of 0.400 cm^2). It is shaped like a circular arc. These curves demonstrate the basic differences between ball and flapper valves. A flapper valve usually has a large segmented CSA as its input port (Shiley's is 0.787 cm^2). A ball valve port is round and has a much smaller CSA (the ball valve is 0.400 cm^2). The large CSA of the flapper valve would make it a very low-impedance device if not for the stiffness of the flap, which requires a small effort on each inspiration. The stiffness causes the valve to have variable impedance, which is highest at the low flow rates that are critical to the patient. A ball valve has much lower impedance in this range. Actually, the impedance of this ball valve is fairly constant.

The ball valve was tested as a clip-on attachment to a No. 6 inner cannula and as a direct twist-lock attachment to the outer cannula. Under the latter conditions, the ball valve proved to be far superior to the commercial valves at all flow rates. When coupled to the inner cannula, the airflow of the ball valve was close to that of the Shiley valve but superior to that of the Passy-Muir valve.

The data used to plot the curves in Fig 6 were obtained under static conditions (ie, the flow rate was increased slowly). This technique is acceptable for measuring the open characteristics of the various valves but not for measuring the closing characteristics. The closing efficiency of the valve can be more accurately ascertained in vivo.

DISCUSSION

In this article a new type of speaking valve is introduced that relies on a ball, rather than a flap or disk, for opening and closing. This valve has been used so far by 125 inpatients and outpatients. The in vitro findings of lower resistance to air translated clinically into enhanced comfort and tolerance and subjectively better voice, as compared with the other commercial valves. In addition, the valve can be connected to or disconnected from the cannula in seconds by any person with reasonable dexterity. Cleaning the valve is simple. First it is soaked in hydrogen peroxide for 10 minutes, and then it is rinsed under tap water and allowed to air dry.

We must stress the importance of the patient's acceptance of a particular speaking valve. Appearance or possible concealment of the valve is very important to many patients. Some of our patients preferred the ball valve to the commercial valves because of its smaller size and because it is easily concealed under light clothing.

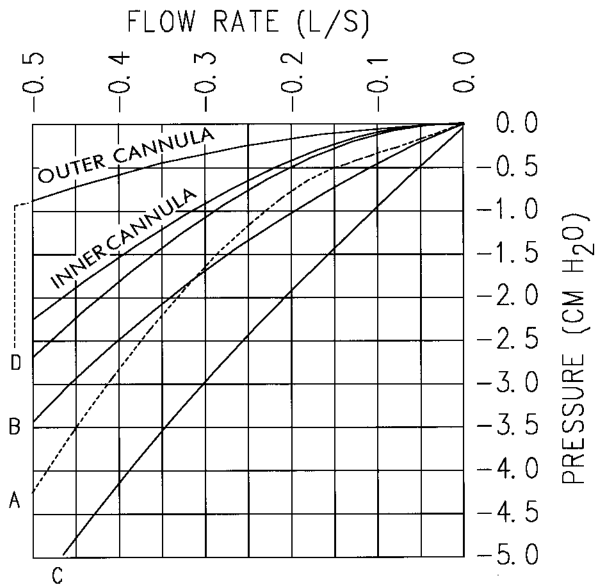

Fig 6. Airflow characteristics of the Shiley *(B)*, Passy-Muir *(C)*, and ball valves *(A)* as they are attached to the inner cannula of a No. 6 Shiley tracheotomy tube, and of the ball valve *(D)* as it is attached directly to the outer cannula of a No. 6 Shiley tracheotomy tube. These are compared with the airflow characteristics of the outer cannula and the inner cannula alone.

In this study, the in vitro airflow/resistance characteristics of the ball valve were compared with those of various speaking valves under standardized conditions. As attached to the inner cannula, the ball valve proved superior to the Passy-Muir valve and equivalent to the Shiley valve. As attached to the outer cannula, it proved superior to both the Passy-Muir and Shiley valves. A controlled study is in progress to objectively compare the clinical characteristics of the different valves, including oxygen saturation, secretion accumulation, olfaction, and acoustic/perceptual evaluation.

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