OBTURATOR AND TRACHEOSTOMY TUBE CONTAINING THE OBTURATOR

BRIEF DESCRIPTION OF THE INVENTION

The invention relates to a flexible obturator of a length sufficient to allow it to extend the length of a tracheostomy tube, i.e., from the proximal to the distal ends thereoff and curving to the shape of the tracheostomy tube. The obturator of the invention possesses a handle at its proximal end and a tip at its distal end, and a plurality of interbonded protrusion and bendable shaft sections sequentially alternating from the handle to the tip. The protrusions extend from obturator's centered elongated longitudinal axis and make contact or come close to making contact with the interior wall of the tracheostomy tube when the obturator is inserted into the tracheostomy tube. Each protrusion is separated from the other by a bendable shaft section and each bendable shaft section is separated by a protrusion. Each bendable shaft section terminates with connections to the protrusions to which it is associated. The distal end of the obturator possesses means for smooth entry of the tracheostomy tube within which it is situated into the trachea. The invention relates to a flexible obturator lodged within a tracheostomy tube possessing flexible walls.

BACKGROUND TO THE INVENTION

Cannula tracheostomy tubes are inserted into the trachea with the assistance of an obturator. The typical obturator has a curved rigid shaft that conforms to the curvature of the cannula within which it is inserted. The obturator is provided with a smooth rounded tip that conforms to the distal opening of the cannula thereby providing a smooth end to the cannula. The function of the obturator is to block the distal opening of the cannula with a smooth surface that facilitates the inserting of the tracheostomy tube into the trachea without appreciably, or to any extent, traumatizing the lining of the trachea.

The conventional shaft of the obturator is angle-ribbed with the ribs extending longitudinally of the shaft's axis. This gives strength to the shaft but also makes the shaft very rigid. As a result, the cannula is assured of being rigid and such rigidity adds to the discomfort to the patient in the insertion of the tracheostomy tube.

Conventional obturators for flexible trach tubes have been made from flat strips of flexible plastic. These obturators can exhibit some severe problems associated with the interaction of the flat strip geometry with the round bore of the trach tube. The flat strip works by engaging the side wall of the tube to position the tip of the obturator in the proper position. However, the flat strip has to contact the wall of the trach tube to maintain its position near the centerline of the trach tube. The contact angle is very undesirable and forms a mechanical wedge of sorts. Since the flat obturator tends to act as a flat spring, it tends to deflect to form a bow shape when forces are applied to the ends.

When the obturator is placed into the trach tube, a frictional force is seen. This frictional force will tend to start the bowing. The bowing will tend to increase with more insertion as the trach tube typically has a curve formed into it in the first place. The bowing causes the flat strip to be pushed into the mechanical wedge as mentioned above. If the coefficient of friction is high enough, this wedging can cause higher insertion force which compounds the wedging problem. In essence, the insertion force will become higher because of the interaction of the materials and the configuration. At an extreme condition, with high friction, this system could constitute a self locking brake and keep the obturator from ever being completely inserted through the trach tube. In addition, the conventional flat strip obturator provides no support for the tracheostomy tube to prevent collapse except on the axis that is coplanar with the plane of the strip of material.

A second type of conventional obturator consists of a small flexible shaft that can bend with two degrees of freedom. While such an obturator can be rigid enough to support the tip, it is difficult, if not impossible, to keep the axis of the obturator coaxial with the axis of the tracheostomy tube. The obturator shaft could follow the inside or the outside wall of the trach tube which have considerably different lengths. This leads to a high variability of locating the tip within the tip of the tracheostomy tube. In addition, such an obturator would provide no support for the walls of the tube during insertion.

A modification of a conventional shaft is described in U.S. Pat No. 5,042,475, patented Aug. 27, 1991. In the description of the obturator of the patent, the shaft of the obturator is a single flat strip that acts like a spring that is dampened in its flexibility by protrusions extending from the surface of the flat strip. The tendency to cause a locking action is diminished by the contact of the protrusions with the wall of the trach tube at a right angle to the potential wedging action. Consequently, the device described in the patents should exhibit lower insertion force and better positioning of the tip than the conventional flat strip obturator. In addition, this design does support the walls of the trach tube during insertion.

There is a desire to make tracheostomy tubes more flexible to afford the patient more comfort. The increased comfort comes from the flexible tracheostomy tube confirming to the patient's anatomy with a low degree of force. The obturator in U.S. Pat 5,042,475 is still essentially rigid in the plane of the main feature of the device, the flat strip that supports the tip and the protrusions. The device has only one degree of freedom for bending. While the device should decrease the insertion force, the rigidity from the flat strip is counterproductive to achieving maximum patient comfort.

There is a need for an obturator that is flexible in two degrees of freedom for bending for patient comfort and is still fairly rigid along is primary axis to position the tip. There is also a need for an obturator that can accomplish the bending while still maintaining accurate coaxial alignment with the associated tracheostomy tube to accurately position the tip of the obturator, that can meet the criteria above and support the walls of the tracheostomy tube during insertion. And finally, there is a need for an obturator that can be used without regard for the rotational alignment of the obturator with respect to the tracheostomy tube. Satisfying these needs are objectives of this invention.

THE INVENTION

This invention relates to a novel obturator with sectionalized flexibility for insertion in tracheostomy tube, especially an obturator designed for adult, neonatal and pediatric tracheotomy applications. This invention relates to an obturator of a length sufficient to allow it and its central longitudinal axis to extend the length of a cylindrical tracheostomy tube, i.e., from the proximal to the distal ends thereof, with sectional flexibility sufficient to bend to the curvature of the tracheostomy tube without inducing undue frictional engagement of the wall of the tracheostomy tube. The