

ENDOTRACHEAL TUBE FIXATION DEVICE AND METHOD OF USING THE SAME

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates to the field of endotracheal tubes and, more particularly, to a device for maintaining the tube in the proper position in the patient's upper respiratory tract.

2. Description of the Prior Art

Patients of all ages may require endotracheal intubation as a life sustaining measure. A frequent complication of endotracheal intubation and airway maintenance is physical trauma caused to the lips, oral membranes, dentitia, gums, larynx, trachea and bronchi. In addition, malpositioned or dislodged endotracheal tubes may result in inadequate ventilation and oxygenation, which can lead to permanent neurological damage and death. Hyperventilation resulting from malpositioned tubes may lead to disturbances of the normal balance between ventilation and perfusion, and life threatening air leak syndromes, such as pneumomediastinum, pneumothorax, and pneumopericardium.

Even with initially properly positioned endotracheal tubes secured by currently available means, intratracheal tube movement and sliding resulting from the vibrations associated with mechanical ventilators and normal patient movements can cause permanent damage to the patient's larynx or airways, such as laryngeal paralysis. In some patients, endotracheal associated damage to bronchial mucosa can result in airway scarring (granulation tissue), hyperplasia (bronchial malacia), resultant airway stenosis, and subsequent increases in both mortality and morbidity.

Conventional methods of endotracheal tube fixation involve placing adhesives, such as tape, or fixation straps externally around the patient's face, neck, head, or lips. For example, see U.S. Pat. Nos. 5,263,478; 5,069,206; 4,683,882; and 3,993,081. Patients suffering from facial burns, dermatitis or cleft palate syndrome are currently dependent upon these externally secured devices, which are very undesirable, painful and impractical. In infants, externally secured endotracheal tube fixation devices are also unsatisfactory because circumferential fasteners around the infant's neck may restrict cerebral blood flow, and application of adhesives directly to the skin can result in dermal degradation.

One available device designed for neonates may be found in U.S. Pat. No. 5,195,513 entitled "Infant Palate Protective Prosthesis," which provides for securing the device externally by conventional methods of taping or strapping. Although the device theoretically provides protection from palatal grooving caused by endotracheal tube movement, it still relies on conventional fixation methods to secure both itself and the endotracheal tube. The use of such a device, therefore, does not address the problems associated with conventional methods, such as dermal damage, decreased cerebral blood flow, or the hazards associated with malpositioned or dislodged endotracheal tubes.

Another common form of prior art device suitable for pediatric and adult populations, but not applicable in infants and neonates may be characterized as a bite block. See, for example, U.S. Pat. No. 5,069,206. In devices of this type, an element of the device is positioned circumferentially, inferior and superior to, or otherwise surrounding the endotracheal tube, and positioned between the patient's upper and lower dentitia. The device is then secured conventionally to

the head and face with tape, external adhesive elements, or strapping. The endotracheal tube is affixed to the device itself with a system of elastic straps or locking clips. Although the device theoretically prevents endotracheal tube occlusion by patient biting, and provides a relatively secure endotracheal tube position, it does not avoid the hazards associated with traditional external fixation methods.

In other available devices, the endotracheal tube is affixed to the device itself by either conventional adhesive methods or with any of a great variety of locking devices. See, for example, U.S. Pat. Nos. 4,360,025; and 4,516,293. However, these fixation means are not satisfactory for effectively preventing endotracheal tube slippage.

Other available devices, such as dental protectors or palatal stabilizers, generally provide a mouthpiece adhered in the patient's oral cavity by an adhesive or a gelatinous insert. Such devices are designed to cover and adhere to the patient's teeth, thereby providing a physical barrier to prevent intubation associated trauma or longer term palatal grooving. These devices, however, do not provide a means for affixing an endotracheal tube in position, but rather are presented as mere protective prosthetics.

Thus, all the prior art devices may be characterized as either external fixation systems or protective prosthetics and are of limited effectiveness. Available external fixation devices are not useful in securing the precise intratracheal position of the endotracheal tube distal tip, nor are they useful, in completely preventing movement or sliding of the tube within the trachea. Further, the prior art devices are associated with the limitations and hazards of conventional external fixation means. None of the devices is suitable for use in all patient populations, and they do not provide adequate protection for the dentitia, lips, gums or upper respiratory tract during insertion of the endotracheal tube.

It should, therefore, be apparent that an improved, simple, inexpensive, protective, internally secured, endotracheal tube insertion and fixation device which is suitable for patients of all ages, is needed to prevent complications and hazards associated with the use of all the prior art devices.

OBJECTS OF THE INVENTION

It is an object of the present invention to provide an endotracheal tube fixation device which can be maintained in a patient's mouth without conventional external adhesive means.

It is a further object of the invention to provide an endotracheal tube fixation device having a means for affixing the endotracheal tube for adjustable positioning without slippage.

It is a further object of the invention to provide an endotracheal tube fixation device having a polymer which is moldable to conform to the particularities of an individual patient's mouth.

It is a further object of the invention to provide an endotracheal fixation tube fixation device which prevents biting occlusion of the endotracheal tube during use.

SUMMARY OF THE INVENTION

The invention provides a medical device for internally maintaining by means of an oral adhesive composition an endotracheal tube in proper position in a patient's mouth and protecting the patient from endotracheal intubation associated injury. The invention provides a device which secures the endotracheal tube in the desired position, and subse-