

**MEDICAL TUBE SECURING DEVICE**

## REFERENCE TO RELATED APPLICATIONS

This application claims the benefit of U.S. Provisional Application No. 61/102,910 filed Oct. 6, 2008, the entirety of which is specifically and entirely incorporated by reference herein.

## RIGHTS IN THE INVENTION

This invention was made with support from the United States Government and, specifically, the United States Army Institute of Surgical Research and, accordingly, the United States government has certain rights in this invention.

## FIELD AND BACKGROUND OF THE INVENTION

The invention relates generally to a novel device for securing medical tubes and catheters intubated within a patient.

Endotracheal intubation, placement of a tube into the trachea, is an integral part of airway management in modern-day medical practice where among the variety of concerns are guaranteeing a patient airway, delivery of oxygen to the lungs, and allowing for the removal of expectorant. Intubation plays a vital role in unconscious patients, patients under or emerging from general anesthesia, victims require acute resuscitation, and various patients need chronic or critical intensive medical care.

In various medical procedures, it is common to introduce a catheter into a patient's airway through the mouth. One type of catheter is an endotracheal tube, which is adapted to be inserted through the oral cavity of a patient and into the trachea, for example, to provide for the supply of fluids to the body, for the monitoring of internal conditions in the body and for removal of secretions from within the body. Other examples of catheters include respiratory tubes for laryngeal masks, oral gastric tubes, and esophageal stethoscopes.

After intubation, patient's airway is reasonably secured but not guaranteed. Failure to fasten an endotracheal tube properly may cause dislodgment or displacement of the tube, or even accidental extubation. These complications usually are life-threatening or even fatal.

Another problem is that the catheter is usually relatively easy to deform as it passes between the patient's teeth when inserted orally, it is desirable to prevent the lumen of the catheter from being occluded by a patient's teeth when the patient attempts to bite down. Occlusion of the catheter can lead to, for example, hypoxia, hypercarbia, and the syndrome known as negative pressure pulmonary edema. The endotracheal tube may be kinked, dislodged, or accidentally extubated or being bitten by the patient, particularly when the patient is semiconscious and not paralyzed. The situations are usually fatal particularly when a wire reinforced endotracheal tube is used.

A number of approaches have been proposed to address the problems presented above. Bite blocks can be effective in keeping a patient's jaw open and thus prevent the teeth from clamping down on the catheter. One problem with a bite block is that it may get loose within the oral cavity and move from its position down into the patient's throat or airway. If this occurs, then the airway may become partially or completely blocked. Another problem inherent with the use of bite blocks is that they typically concentrate the force exerted by the

patient's mandibular contraction on one or two incisors resulting in documented instances of dental disruption and loss.

Presently, adhesives are used to keep the tube positioned which are ineffective because of the presence of facial hair, oily skin, dirt, blood, etc. According to this approach of retaining a medical tube near the tube insertion site, one or more adhesive strips are applied directly over the tube and to the skin of the patient. In order to adjust the position of the tube, the adhesive strip must be removed from the skin and then reapplied in the desired location. This significantly weakens the holding strength of the adhesive, and often requires the placement of additional strips on the tube and skin to properly anchor the tube. Natural body secretions further reduce the ability of the strip to properly retain the tube.

Alternatives to adhesives are known in the art, including the use of straps and harnesses used to secure the medical device around the patient's oral cavity. A common problem with this technique, however, is that the strap rubs against the cheeks and the sensitive tissue at the corners of the mouth, resulting in angular cheilitis (also called perlèche, cheilosis or angular stomatitis) and infection. This is even more of a problem when a patient presents with burns on the face, head and neck which preclude the use of adhesives or irritating straps due to the delicate condition of the affected skin.

U.S. Pat. No. 5,655,519 to Alfrey discloses a patient airway bite block that may be used together with laryngeal mask airways, oral endotracheal tubes and similar patient airways (col. 1, lines 4-7). The bite block comprises a handle for positioning the bite block within the patient's mouth and for removing the bite block therefrom (col. 3, lines 53-58; col. 8, Lines 25-43; FIGS. 1, 5 and 7). The Alfrey device does not address the problem of preventing damage to the skin of the patient, particularly the corners of the mouth. Indeed, the handle of Alfrey is in direct contact with the corners of the patient mouth and would stay in direct contact, causing irritation and subsequent tissue damage, for as long as the Alfrey device is being used on the patient for airway control (FIGS. 7 and 8).

U.S. Pat. No. 5,490,504 to Vrona et al., sold on the market as the ANCHOR FAST™ Oral Endotracheal Tube Fastener by Hollister, Inc., Libertyville, Ill. discloses an endotracheal tube attachment device for positively securing an endotracheal tube to a patient and allowing selective lateral positioning of the tube without removing the same from the patient by means of a tracked device (Abstract; FIG. 5). The Vrona device does not address the problem of keeping a patient's jaw open to prevent the teeth from clamping down on the catheter, or the commensurate problem of dental disruption and loss due to long term mandibular contraction. Furthermore, the Vrona device does not address the problem of preventing damage to the skin of the patient, particularly the upper lip and cheeks (col. 4, lines 10-18; FIG. 5), making the device unsuitable for use with burn victims and patients with sensitive skin.

Therefore, there exists a need for a medical tube securing device that addresses the problems inherent with current bite blocks, straps and harnesses.

## SUMMARY OF THE INVENTION

A medical tube securing device for a patient is disclosed, comprising at least one bite block and a support frame integral with said bite block, said support frame comprising a protruding extension with at least one inwardly recessed portion.