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New intraoral device for prevention of oral lesions in intubated patients

Novo dispositivo intraoral para prevenção de lesões bucais em pacientes intubados

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ABSTRACT

Oral injuries in patients in Intensive Care Units (ICU) are recurrent, especially during endotracheal intubation, as the presence of the tube added to the teeth in the oral cavity can cause injuries to the tongue and other soft tissues. Ideally, tube stabilization devices should be easy to handle by the hospital staff, should always be available for use in ICUs, in addition to being low cost. The aim of this study was to develop a device for endotracheal tube stabilization and injury prevention in patients. 3D technical drawings were prepared, and the final version of the device was prototyped in polylactic acid and positioned in the patient. When compared to mouthguards described in the literature, it was found that the developed device provided stability for the tube, provided separation of the teeth from the adjacent soft tissues, and prevented the intubated patient from biting the tube, thus contributing to the prevention of traumatic injuries. It was concluded that the device has characteristics that allow stabilization of the endotracheal tube and the prevention of oral lesions in ICU patients, and can be used by hospital nursing staff.

Keywords: Dental surgeon. Health. Intensive Care Unit.

RESUMO

Lesões bucais em pacientes em Unidades de Terapia Intensiva (UTI) são recorrentes, em especial quando há intubação endotraqueal, pois a presença do tubo adicionada aos dentes na cavidade bucal pode causar injúrias à língua e a outros tecidos moles. Idealmente, dispositivos de estabilização do tubo necessitam ser de fácil manejo pela equipe hospitalar, precisam estar sempre disponíveis para uso nas UTIs, além de apresentar baixo custo. O objetivo deste estudo foi desenvolver um dispositivo para estabilização de tubo endotraqueal e para prevenção de lesões em pacientes. Desenhos técnicos 3D foram confeccionados, sendo a versão final do dispositivo prototipada em ácido polilático e posicionada em paciente. Quando comparado aos protetores bucais descritos na literatura, verificou-se que o dispositivo desenvolvido conferiu estabilidade do tubo, proporcionou o afastamento dos dentes dos tecidos moles adjacentes e impediu que o paciente intubado mordesse o tubo, contribuindo para a prevenção de lesões traumáticas. Concluiu-se que o dispositivo reuniu características que permitem a estabilização de tubo endotraqueal e prevenção das lesões bucais em pacientes de UTIs, podendo ser utilizado pela equipe de enfermagem de hospitais.

Palavras-chave: Cirurgião-dentista. Saúde. Unidade de Terapia Intensiva.

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INTRODUCTION

The integration of Dentistry into multidisciplinary teams in hospital settings has proven effective in the overall treatment of patients, disease prevention, and greater humanization in the treatment of patients interned in Intensive Care Units (ICU) (Blum, Silva Baeder & Bona, 2018). Dentistry stands out as a specialty that acts in varied situations in ICUs, contributing to the diagnosis of oral pathologies, in the proposition of procedures necessary for the reduction of infections caused by nosocomial microorganisms and lesions in oral mucosa, and in the reduction of costs resulting from the worsening of patients' health (Bellissimo-Rodrigues et al., 2018).

The importance of studies on oral health in ICUs has been a recurring theme (Jun et al., 2021). In this scenario, oral disorders and systemic worsening factors in patients using respirators stand out. The use of a respirator or mechanical ventilator is common in individuals who are temporarily or permanently unable to breathe spontaneously through normal routes due to disease, anesthesia and congenital anomalies (Santos et al., 2020). In ICUs, the equipment is connected to the patient via an endotracheal tube or tracheostomy. When placed endotracheally, the oropharyngeal condition may be related to the transmission of nosocomial microorganisms (Guimarães & Rocco, 2006; Othman & Abdelazim, 2017). Dental biofilm, in users of mechanical ventilation equipment in the ICU, represents a source of pathogens that cause pneumonia (Sands et al., 2017), which is aggravated by the difficulty of performing oral hygiene (Luca et al., 2017).

Intubated ICU patients are at risk of developing mouth and lip injuries caused by pressure from endotracheal tubes (Hampson et al., 2018). Some professionals have used adapted sports mouthguards to prevent and treat these injuries, as the treatment of these injuries may be associated with an improvement in the patient's clinical condition (Kiat-Amnuay, Koh & Powner, 2008).

Several requirements are listed for a trauma protection and prevention device (Hanson, Ogle & Giron, 1975): it must move tissues that may be damaged by involuntary jaw movements away from the occlusal plane; it must not cause damage to the patient's oral mucosa; it must allow mandibular movements; it must resist the forces of rupture and displacement; it must allow healing of traumatized oral tissues; it must be easily manufactured and installed without discomfort or risk to the patient and be amenable to daily oral care. These characteristics are necessary to prevent appliances from aggravating a problem already present in the patient, since a rupture or breakage of parts of materials can cause aspirations and/or lacerations, fractures in the occlusal and incisal surfaces of the teeth (Davis, 1989). Appropriate mouthguards can prevent bleeding and problems associated with infection, as well as promote healing of lacerations in the oral cavity. Additionally, the cost related to the acquisition of a mouthguard would be less than that of the treatment of infections (Avashia, Bittar, Suresh & Powers, 2018).

Aware of the importance of injury prevention in patients with endotracheal intubation in ICUs, this study aimed to develop and test a device model that provides endotracheal tube stabilization and prevents oral injuries in patients with oral intubation in ICUs, and that may be available for use in these units.

MATERIAL AND METHODS

Intraoral device development and testing

This research was submitted to *Plataforma Brasil*, and was approved under CAAE registration: 797302117.0.0000.0077. Technical 3D drawings were prepared using SolidWorks software until the final version of the device was achieved, which was then printed in polylactic acid (PLA) in a 3D printer, Sethi 3D model. Polylactic acid, the main filament used in 3D printers, is a non-toxic, semi-crystalline or amorphous aliphatic polyester that is biodegradable and biocompatible with the human body (Besko, Bilyk & Sieben, 2017). Due to its properties, PLA has been commonly used in the food, pharmaceutical and medical industries (Davachi & Kaffashi, 2015). The device is

made of a resistant material, autoclavable, a single unit with adult and child sizes available. Figures 1, 2 and 3 illustrate the protector and its components.

The device has a central hole (11a) that acts as a channel for the passage of the endotracheal tube and, as it is made of rigid material, it helps avoid obstruction of the tube by preventing the patient from biting the tube. (Figure 1).

In its frontal portion, the prototype presents itself as a shield formed by a thin laminar piece with an oblong and arched shape. Near the extreme edges, there are cutouts (11b) that allow the visualization of the patient's mouth and the insertion of a secretion suction probe, as well as small orthogonal projections (11d) in the form of a "T" that make external fixation feasible, thus enabling greater stability of the prototype on the patient's face. In its extraoral region, there are small holes (11c) designed as alternatives for device fixation.

The inclusion of a frontal hook (11e) in the external shield of the prototype, close to the central hole for insertion of the endotracheal tube, will allow greater fixation of the endotracheal tube. The tube can be fixed using a tape, ribbon, elastic band or even a shoelace without causing injuries to the patient's lips, providing greater comfort for the patient and practicality in handling. The device also has an extension (12) to accommodate lips and teeth.

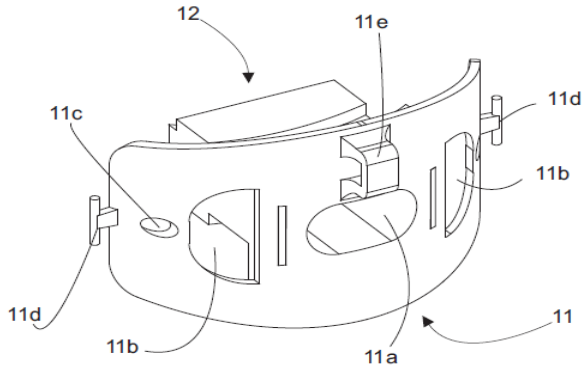


Figure 1. Front perspective drawing of the mouthguard. Key: protective shield (11), central hole (11a), side openings (11b), small holes to assist in fixing the device (11c), orthogonal projections as external options for external attachment of the protector (11d), front hook (11e), extension for removal, rest and accommodation of the patient's lips and teeth (12).
Source: The authors.

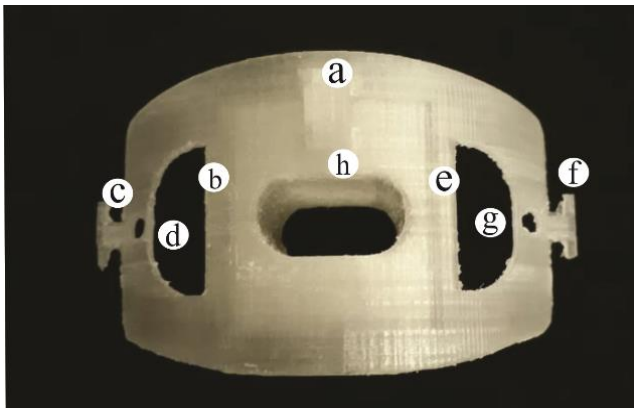


Figure 2. 3D printed part (front view). Key: front attachment (a), side openings (b, e), optional fixing holes (d, g); stem used for optional fixation, (c, f), central hole for passage of the endotracheal tube (h).
Source: The authors.

In its intraoral section, there is a hole with an opening of 11 mm in diameter for adults and 9 mm in diameter for pediatric patients. In the posterior portion of the device, there is an extension (12) for retraction, rest and accommodation of the patient's lips and teeth; the said extension (12) has a 'T' section, with steps closer to the frontal shield (12a) that configure stops for the accommodation of the region of the lips and that develop in projection (f1) of smaller width with the upper and lower faces that configure tracks for the accommodation of the patient's teeth. Next to the extreme portion of the projection (12b), a region is provided for material accumulation (12c) with greater width (I3) that represent stops to prevent the sliding of the teeth towards the posterior portion; on the posterior surface of the extension (12) a pair of triangular-shaped projections (12d) develop obliquely and form flaps to separate the buccal mucosa (Figure 3).

The edges of the inner portion of the mouthguard are rounded to avoid injury to the patient, since the entire body of the device is in the intraoral region and in intimate contact with the patients' mucous membranes, and involves the anterosuperior and inferior regions of the patient's mouth, contributing to the fact that the protector can be used by adult and pediatric patients, avoiding the need to make it in different sizes. However, in cases of patients with extremely large or small body sizes, devices with different sizes can be produced. In this way, the prototype measurements could be altered to meet specific demands.

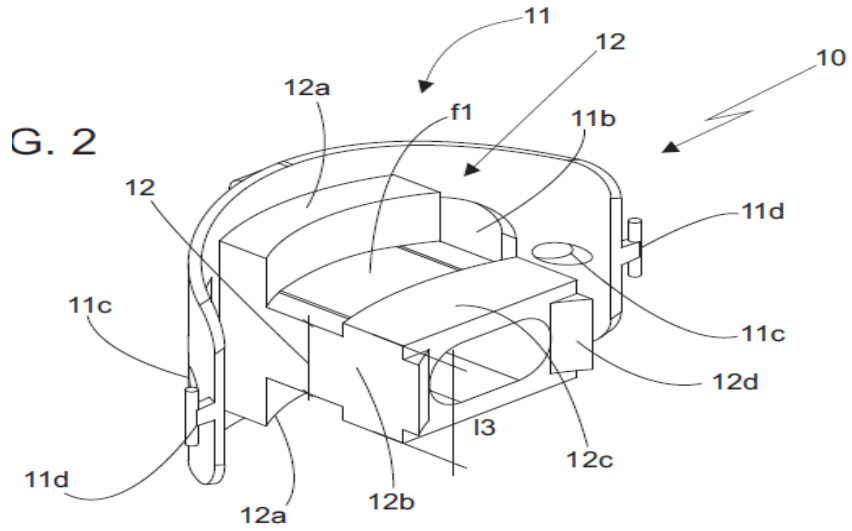


Figure 3. Rear perspective drawing of the mouthguard. Key: device (10), protective shield (11), side openings (11b), small holes to assist in fixing the device (11c), orthogonal projections as external options for external fixation of the protector (11d), extension for withdrawal, rest and accommodation of the patient's lips and teeth (12), anterior stop to accommodate the region of the lips and prevent the sliding of the teeth towards the anterior portion (12a), projections (12b), stop to limit the teeth in the groove preventing the sliding of the teeth for posterior portion (12c), pair of projections that represent fins (12d), channel for accommodation of teeth, upper face (f1), wider region (13).
Source: The authors.

A clinical test was performed with an individual at the Hospital Municipal José de Carvalho Florence (São José dos Campos, SP, Brazil) to assess the stability and positioning of the prototype. A Free and Informed Consent Form, previously submitted to *Plataforma Brasil* and approved, was collected for the test. The model patient did not have multiple anterior tooth absences which would have made it difficult to adapt the protector and would have a lower risk of developing oral lesions. The protector proved to be stable in the model patient's oral cavity (Figure 4A), providing stability to the tube, allowing the teeth to be removed from the adjacent soft tissues and preventing the patient from biting the tube, thus contributing to the greater comfort of the individual when compared to the procedure commonly used to fix the orotracheal tube in the ICU (Figure 4B). Testing to assess the use of the protector for a long period will still be necessary. We emphasize that to reduce the risk of accidental extubation, at the time of aspiration by professionals of the multiprofessional team or at the time of oral hygiene, we recommend additional fixation of the endotracheal tube as usually used.

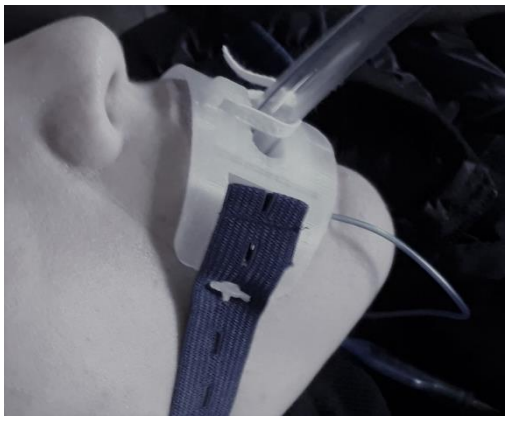
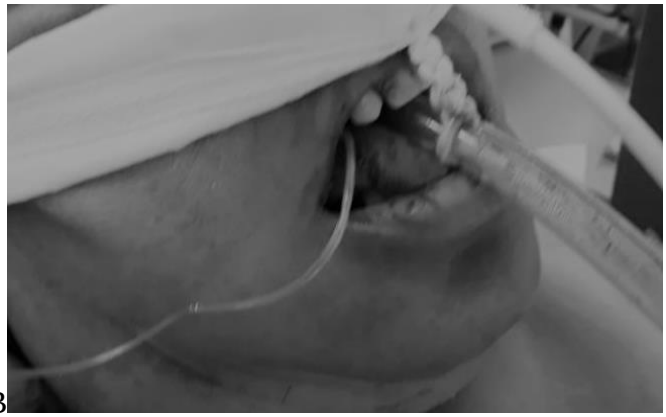
A  B 

Figure 4. Model patient using the prototype (4A) and patient with external fixation of the endotracheal tube as usually used (4B).
Source: The authors.

RESULTS AND DISCUSSION

To optimize the use and efficiency of protectors for injury prevention in ICU patients, a device that is simple in structure, stable and has the ability to distance soft tissues from the teeth and low cost is recommended (Davis, 1989). The proposed protector presents important characteristics to offer greater practicality in handling the piece by health professionals, and better patient comfort compared to the models previously proposed (Davis, 1989; Craft, 1999; Yamanaka et al., 2014; Franco et al., 2015; Sijeria et al., 2017): a) a small “shield” that will make external fixation possible, thus providing stability for the protector on the patient's face; b) lateral openings that will facilitate the visualization of the patient's mouth and the introduction of a probe to aspirate secretions; c) the inclusion of a hook in the external shield of the prototype, close to the endotracheal tube insertion hole, will provide fixation and stabilization of the endotracheal tube without causing injuries to the patient's lips and will prevent accidental extubation; d) the short inner portion will provide comfort to the patient; e) being a removable device, it allows adequate hygiene. When tested on a patient, it was possible to verify that its anatomical shape allowed the removal of adjacent soft tissues, contributing to the prevention of injuries. Additional fixation of the endotracheal tube is recommended to minimize the risk of accidental extubation for patients using the device.

In a comparative analysis between the intraoral device developed in the present study and models described in the literature, it can be observed that most of them are made individually, requiring previous impressions and, in many cases, the preparation is carried out in the laboratory (Hanson et al., 1975; Kiat-Amnuay et al., 2008; Yamanaka et al., 2014; Chaudhary, Bodh, Sharma, Mohanty & Verma, 2018) including a prosthetic step, which takes time. In patients with involuntary movements, these impressions should be performed while the patient is under sedation or general

anesthesia (Franco et al., 2021). In addition, the materials used for impression can come loose, making the procedure risky. Therefore, the molding factor should be avoided in the ideal prototype. Currently, we rely on digital impressions (Imburgia et al., 2017), however, the fact that the patient is intubated would make scanning difficult.

Some devices aimed at preventing these injuries in ICU patients were developed from materials such as acrylic resin, rubbers and polymeric materials (Hanson et al., 1975; Kiat-Amnuay et al., 2008; Chaudhary et al., 2018). The ideal material should offer comfort to the patient and preferably be autoclavable, which offers the possibility of being reused and made available in the routine care of intensive care units. For this reason, PLA was chosen; a material commonly used in the food, pharmaceutical and medical industries (Davachi & Kaffashi, 2015) because it has favorable characteristics in these applications: non-toxic, semi-crystalline or amorphous aliphatic polyester, biodegradable and biocompatible with the human body. (Ghalia & Dahman, 2017; Sousa, Pinho, Messias & Piedade, 2020).

For future perspectives, the use of digital software and 3D printing are being promoted as alternatives for manufacturing mouthguards. This approach would provide protectors with greater precision in thickness and design details (Sousa et al., 2020). We emphasize that the material for making the large-scale prototype should preferably be made in an injected form and in an autoclavable material to allow multiple uses. There are several types of materials used in the health area that meet these requirements, and among them are polymers, such as: polyetheretherketone (PEEK); polyphenylsulfone (PPSU); and polysulfone (PSU). The final choice of material is at the discretion of the manufacturer, who must take into account other requirements such as material availability and associated costs (Sant Anna, 2014).

Although the presence of dental surgeons is not yet consolidated in hospitals, the actions of these professionals and their integration into the multidisciplinary team contribute to the best plan for care and recovery of patients (Cortizo et al., 2014; Carvalho, Souza, Câmara, Ribeiro & Pierote, 2020). Based on this research, we emphasize the role of Dentistry in the hospital environment, especially in ICUs, as a specialty that is active in several situations, from the diagnosis of oral pathologies to the proposition of necessary procedures for oral health, maintenance of comfort, and patient's quality of life (Gupta & Stuart, 2020; Winning, Lundy, Blackwood, McAuley & Karim, 2021).

CONCLUSION

The device developed in the present study combined characteristics that facilitate the prevention of oral lesions in ICU patients, since it encourages disocclusion and reduces the contact of teeth with the tongue, and can be used in a simple and systematic way by hospital nursing staff. The use of the proposed mouthguard also prevented the patient from biting the endotracheal tube, which is a recurrent problem within the ICUs.

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