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Original Article

Feasibility Test of Three Dimensional Intermittent Oro-Esophageal Tube Guide for Dysphagia; Biocompatibility and Pilot Case Study

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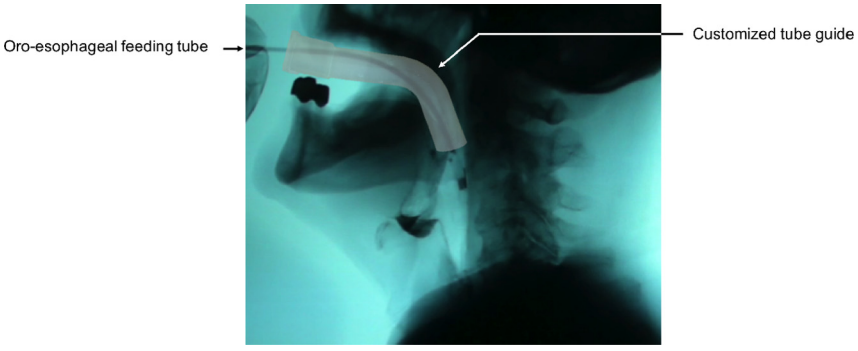
Highlights

- Patient-customized tube guide was designed as an insertion guide of feeding tube.
- The customized tube guide three-dimensionally printer with polylactic acid.
- The customized guide group spent less time in the insertion of the feeding tube.

Graphical abstract



Abstract

Background: In our previous study, oropharyngeal airway was beneficially tested as insertion guide of intermittent oro-esophageal (IOE) tube for feeding of dysphagia patients. As advanced investigation, patient-customized tube guide was designed based on a soft neck radiography image of the patient, and fabricated using three-dimensional printer with polylactic acid (PLA).

Methods: Before clinical trial of the 3D-printed tube-guide, biocompatibility of the 3D-printed PLA plate is tested. The biocompatible tube-guide was tried on three consenting subjects.

Results: Despite its small cohort size, the customized tube-guide group spent less time in the insertion of the IOE tube than the only IOE tube group.

Conclusion: This tendency increases feasibility of the customized IOE tube. We are still recruiting subjects for statistical significance of our trial.

Keywords: Dysphagia; Tube guide; Three-dimensional printer

1. Introduction

A term of dysphagia characterizes difficulty in swallowing nutritious substances [1,2]. Dysphagia commonly occurs in el-

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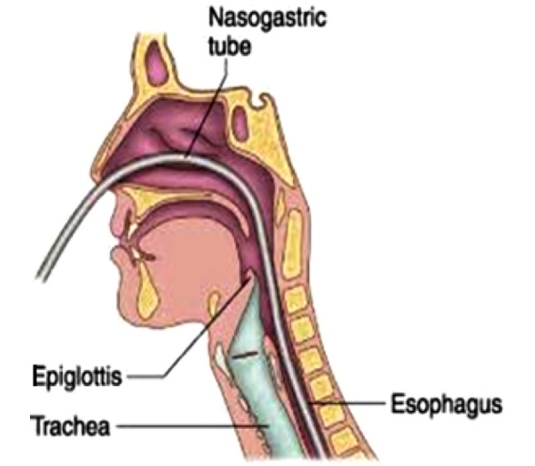
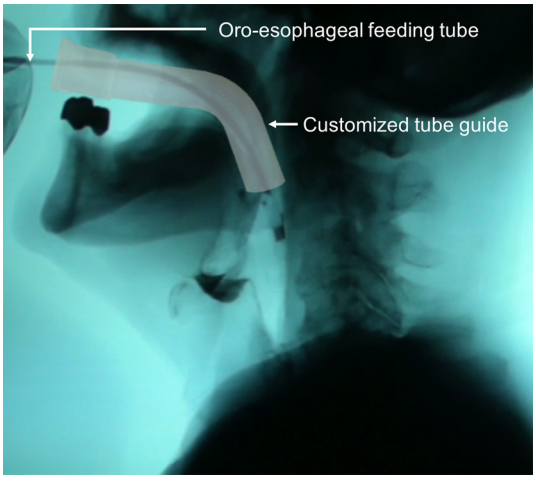


(a)



(b)

Fig. 1. The conceptual images of (a) the continuous nasogastric tube feeding, (b) the intermittent oro-esophageal tube feeding using the proposed customized tube guide.

derly people after strokes involving both cerebral hemispheres and the brainstem [2,3]. Dysphagia provoked by an acute stroke is a reported incidence as high as 47%. Its typical symptoms are drooling, dysmasesis, delay of swallowing, cough, asphyxiation and aspiration pneumonia [3–5].

Dysphagia may cause malnutrition, dehydration, aspiration pneumonia or pulmonary aspiration [1,5,6]. A proper feeding method is required to avoid these secondary symptoms. The general methods for nutritional support include parenteral nutrition and enteral nutrition [6–8]. The enteral nutrition is regarded as more suitable for patients with an intact intestinal tract because the parenteral nutrition could induce insufficient nutrition and bacterial infection [8,9]. The enteral feeding methods include nasogastric tube feeding and percutaneous endoscopic gastrostomy feeding [8]. The continuous nasogastric (CNG) tube feeding (Fig. 1(a)) is a practical technique for coma patients. However, the CNG tube feeding leads to accidental displacement with the associated risk of pulmonary aspiration [10,11]. Furthermore, other problems can occur such as inflammation, restriction of oropharyngeal movement, gastroesophageal reflux, diarrhea, and aspiration pneumonia. Therefore, the nasogastric tube is recommended to use only for a short time [12]. The percutaneous endoscopic gastrostomy feeding method is one of the most conventional methods with 15–30 minutes procedure time and over 95% success rate [13,14]. However, the patients are often at high risk for complications such as bleeding, infection, diarrhea and reflux from the surgical procedures [14].

Intermittent oro-esophageal (IOE) tube feeding was introduced by Campbell-Taylor, et al. in 1985 [15]. The IOE tube feeding is a method of providing enteral nutrition for dysphagia patients without any invasive procedure. A feeding tube is inserted through the mouth into the esophagus so that this method reduces incidence of complications such as pneumonia, diarrhea, and reflux [7,15]. Even though the IOE tube feeding can be applied in both conscious and unconscious patients, complications of the IOE tube also have been reported in the unconscious patients [3,16]. In the conscious patient cases, it is difficult to apply the IOE tube feeding to patients with upper limb weakness, because the IOE tube needs to be inserted by the patients themselves. In the upper-limb-weak patient and the unconscious patient cases, a caregiver can insert the IOE tube and feed food through the inserted IOE tube for those patients. Despite of the caregivers' help, it is difficult to exclude the possibility of aspiration pneumonia, because the tube can be displaced into the larynx or can lead to torsion within the pharynx [16]. These factors limit utilization of the IOE tube.

In order to overcome these limitations our group investigated feasibility of oro-pharyngeal airway (OPA) for secure guide of the IOE tube [17]. The IOE tube insertion with the OPA showed decreased insertion time comparing that without the OPA (17.72 ± 5.79 seconds vs. 25.41 ± 10.41 seconds; $p = 0.017$). Despite of the decrease in the tube insertion time, the OPA method has chance to guide the IOE tube incorrectly because of its few design choices based on the standard oral size.

Our group fabricated mannequin-customized tube guide using three-dimensional (3D) printer [18]. The 3D printer system fabricates a three-dimensional structure layer-by-layer of cross-sectional slices with respect to user's three-dimensional design [19,20]. Even though the 3D printer system fabricates one three-dimensional structure at one time, it can fabricate the three-dimensional structure in comparably short time with respect to design change [20]. Currently the 3D printer applies to customized products with small volume such as prototypes, mockups, replacement parts, medical stuff, and so on [20]. Fig. 1(b) shows the conceptual image of the IOE tube feeding using the 3D-printed tube guide. We have designed and 3D-printed five types of the customized IOE tube guide not to touch gag reflex point. Two types of the IOE tube guide (Fig. 2) have escorted the IOE tube to esophagus securely in the mannequin test.

In this study, we propose a patient-customized IOE tube guide fabricated by a 3D printer and investigate its clinical case study. Based on our experience of the mannequin study, we propose a patient-customized IOE tube guide design technique using a simple coronal and sagittal radiography of the patients' cervical spine and neck. Before the 3D printing, bio-

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