Mannequin Evaluation of 3D-Printed Intermittent Oro-Esophageal Tube Guide for Dysphagia

Yujin Jeong, Youkyung Son, Myounghwan Choi, Sanghyub Lee, Sangyeol Lee, Changho Hwang, Kyo-in Koo

***Abstract*—**Dysphasia is difficulty in swallowing food because of oral cavity impairments induced by stroke, muscle damage, tumor. Intermittent oro-esophageal (IOE) tube feeding is one of the well-known feeding methods for the dysphasia patients. However, it is hard to insert at the proper position in esophagus. In this study, we design and fabricate the IOE tube guide using 3-dimensional (3D) printer. The printed IOE tube is tested in a mannequin (Airway Management Trainer, Co., Ltd., Copenhagen, Denmark) mimicking human's esophagus. The gag reflex point is measured as the design point in the mannequin. To avoid the gag reflex, we design various shapes of IOE tube guide. One structure is separated into three parts; biting part, part through oral cavity, connecting part to oro-esophageal. We designed 6 types of IOE tube guide adjusting length and angle of these three parts. To evaluate the IOE tube guide, it is inserted in the mannequin, and through the inserted guide, an endoscopic camera successfully arrived at the oro-esophageal. We had planned to apply this mannequin-based design experience to patients in near future.

***Keywords*—**Dysphagia, feeding method, IOE tube guide, 3-D printer.

I. Introduction

THE capacity to swallow or eat is a basic human need and can be a great pleasure [3]. The term of dysphagia characterizes difficulty in swallowing nutritious substances [12]. Dysphagia commonly occurs in elderly people after strokes involving both cerebral hemispheres and the brainstem [8], [9]. Dysphagia provoked by an acute stroke is a reported incidence as high as 47% [2].

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

An IOE tube feeding was introduced by Campbell-Taylor et al. in 1985 [5]. The IOE is a method of providing enteral nutrition for dysphagia patients without any invasive procedure. The feeding tube is inserted through the mouth into the esophagus for intermittent nutrition supplying so that this method reduced the incidence of complications [5], [10]. 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 unconscious patients [2], [13]. 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 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 [13]. These factors limit utilization of the IOE tube.

In order to decrease complication risk of the IOE tube method, we propose a patient-customized IOE tube guide using 3D printer. The proposed tube guide is inserted from dysphasia patients' mouth, and secures the IOE tube's route from teeth to oro-esophagus without any risk of mal-navigation to a respiratory tract. For this performance, the proposed tube guide should be patient-customized. In this study, as a preclinical step, we design our tube guide in the basis of a mannequin size. For the mannequin-customized fabrication, 3D printer is utilized. The 3D printer system fabricates a 3D structure layer-by-layer of cross-sectional slices with respect to user's 3D design. Even though the 3D printer system fabricates one 3D structure at one time, it can fabricate the 3D structure in comparably short time with respect to design change. Currently, the 3D printer applies to customized products with small volume such as prototypes, mockups, replacement parts,

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medical stuff, and so on [4].

II. Methods & Results

A. Design Using a Mannequin

For decreasing of complication risk, the proposed IOE tube guide should provide solid and secure route from teeth to oro-esophagus. Because every patient's oral cavity size is different each other, the tube guide should be patient-customized. As a preclinical step, we measure size of a mannequin (Airway Management Trainer, Ambu Co., Ltd., Copenhagen, Denmark) instead of dysphasia patients. This mannequin gives an accurate simulation of mouth, nostrils, teeth, tongue, pharynx, larynx, epiglottis, vocal cords, trachea, oro-esophagus and lungs. It is world-widely used in education institutes including lots of medical schools. For the mannequin-customized design, length and angle are measured between incisor teeth and orifice of the upper esophageal sphincter muscle (corresponding to the entrance of the esophagus) in the mannequin, as shown in Fig. 1. In our mannequin case, the length is measured between the incisor teeth and the soft palate. Drawing the line to the second cervical vertebra (C2) from the soft palate, we measure the angle. The length is 55 mm, and the angle between them is 126 degree.

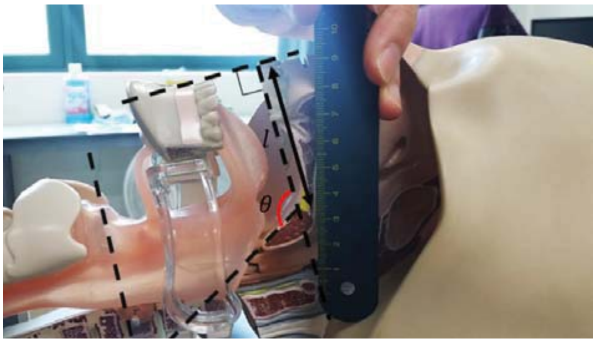

Fig. 1 The measurement of the length and angle about the three points which are indicated each gag reflex points

Another design consideration factor is gag reflex for patients' comfort. The gag reflex is a protective response that prevents unwanted material, e.g., a noxious food bolus or foreign object, from entering the pharynx, larynx, and trachea [7]. The gag reflex evoked by touching the roof of the mouth, the back of the tongue, the area around the tonsils and the back of the throat as shown in Fig. 2. To avoid the gag reflex, the tube guide should pass through to the destination, oro-esophagus, touching as little surface of oral cavity as possible except tongue. Smaller diameter and thinner wall of the tube guide enables less touch on the surface of oral cavity. Considering diameter of the conventional IOE tube (12 mm) and fabrication limit of our 3D printer system (Projet 3510 HD Plus, 3D Systems, Inc., Rock Hill, SC, U.S.A.), inner diameter and outer diameter of the tube guide is varied from 7 mm to 9 mm.

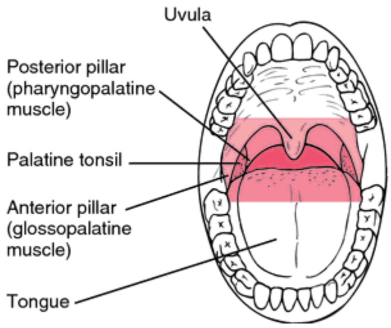

Fig. 2 Areas that react in a gag reflex when touched

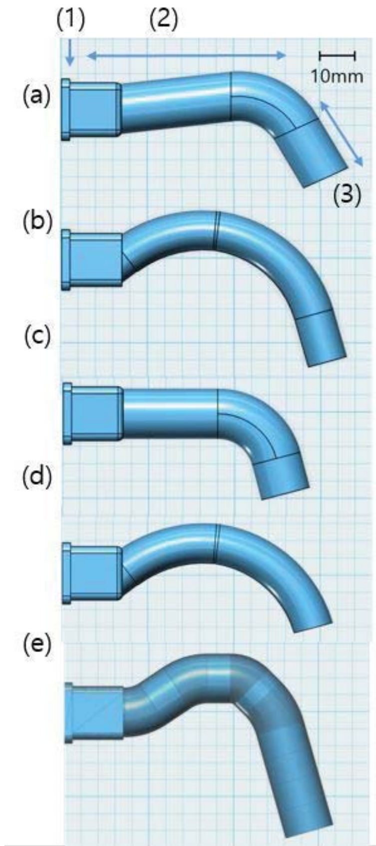

Fig. 3 Some parts of variable design shapes in Autodesk 123d Design

The proposed IOE tube guide consists of three parts; (1) a biting part, (2) a passing part through an oral cavity, and (3) a connecting part to an oro-esophageal, as shown in Fig. 3. This guide has a channel in its body for the IOE tube passing as well. We design 5 types of the IOE tube guide considering the mannequin's size and the gag reflex, as shown in Fig. 3. Design (a) and (c) in Fig. 3 have straight lines in the passing part with different angle between the passing part and the biting part. Considering tongue shape, several round shapes in the passing part are designed as (b), (d) and (e) in Fig. 3. Autodesk 123d (Autodesk, Inc., U.S.A) is used as a 3-d designing tool [1].

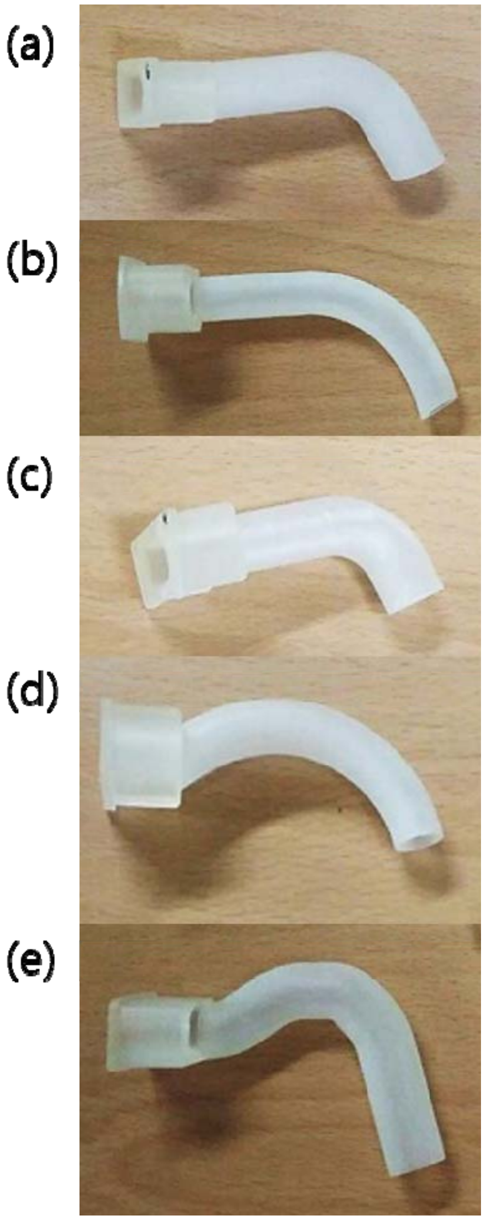

Fig. 4 The modeling shapes printed by 3-D printer

B. Printing & Testing

Our 5 designs of the IOE tube guide are 3D-printed by an inkjet type 3D printer system with photo-curable resin (Visijet M3 Crystal, 3D Systems), as shown in Fig. 4. In some fabrication cases, surface of the printed guide is little bit rough. However, it does not make any matter in insertion tests.

The printed tube guides are inserted from mouth of the mannequin. After the insertion, an endoscopic camera (BU007, Lightcom Co. Ltd., Korea) passes through the inserted tube guides recording inside of the printed tube guides. When inserted from the mouth, the type (d) and (e) touch the gag reflex point. Fig. 5 shows that the type (e) bump the gag reflex points due to round structure of the passing part. The connecting part of the type (c) is too short to reach the destination, the oro-esophageal. Conclusively, the type (a) and (b) successfully guide the endoscopic camera to the esophageal as shown in Fig. 6. After the successful guide of the endoscopic camera which has 5 mm diameter, a conventional IOE tube with 12 mm diameter also is guided properly to the oro-esophagus. In our experience of the mannequin test, length of the connection part ((3) in Fig. 3) could be shorter than our design because the angle between the connection part and the passing part looks guiding the passing tube more properly rather than the length. For the clinical application, material of the tube guide should endure mastication force of the dysphasia patient’s. Even though we do not measure how much force our printed tube guide support, it does not show any scratch nor crack to biting of the mannequin manipulated by human hands.

Fig. 5 Insertion of the printed (e) type IOE tube guides stimulus the gag reflex points in the mannequin

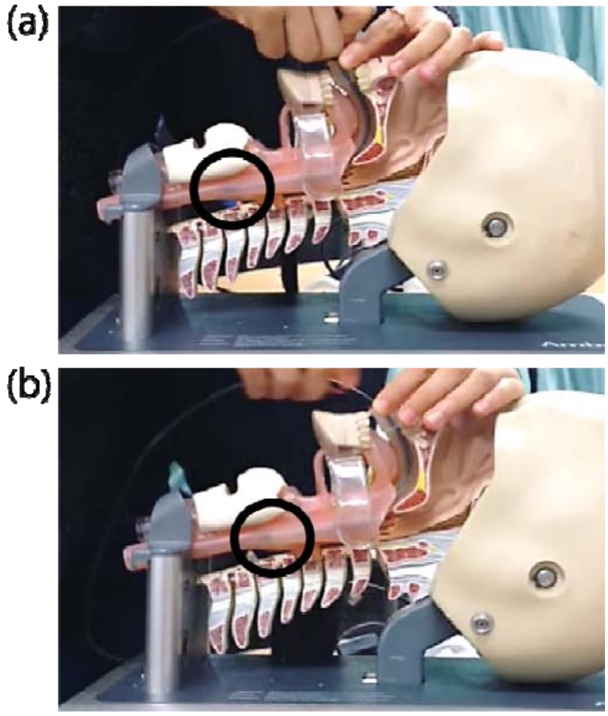

Fig. 6 Captured the recording file which is inserted the two shapes ((a): type of Figs. 4 (a), (b): type of Fig. 4 (b)) in the mannequin. The endoscope camera arrived at esophagus through the two shapes. It is indicated in the circle

III. Discussion & Conclusion

In this study, we designed 5 types of the IOE tube guide on the basis of the mannequin size, fabricate the designed tube guide using 3D printer system, and evaluate the fabricated tube guide using the mannequin. Among the 5 types design, comparably simple design types ((a) and (b) in Fig. 2) guide without any mal-navigation to the respiratory tract. From the mannequin-based design and test, we accumulate design know-how for the patient-customized tube guide design.

In order to move up the next step, biocompatibility of the photo-curable resin, Visijet M3 Crystal, the main material of the printed tube guide, should be checked. Medical image source of the dysphasia patient is also important factor for the practical application. Even though 3D computed tomography image of the patient is fertile source for the tube guide design, its cost and time are much higher than one single X-ray image. However, designing based on one single X-ray image could be shortage of design information for the patient-customized tube guide. Currently we are investigating the patient-customized IOE tube guide.

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