INTRODUCTION

There has been no advancement in the past century in the tools used for oropharynx examination, which is currently performed using a light source such as an electric light, penlight, or forehead mirror to illumine a desired visual field using a tongue depressor. It is extremely difficult to obtain objective recorded evidence for display with these methods, and the tools for examination have remained virtually unchanged for the past century. Treatment of the pharynx/oral cavity is exceedingly difficult, particularly in elderly patients and children. Therefore, there is an increasing need to develop a method for displaying the visual field during oropharyngeal examinations which is acceptable to patients, which can be easily applied at all medical institutions, which can be displayed to third parties, and which can be used by doctors for recording data and determining treatment. We earlier developed a dedicated device for this purpose (Improved Type I) and have now made further improvements. This study aims to evaluate the utility of the improved type II oropharyngeal endoscope as a tool for objective examination.

Key words tongue depressor, oropharyngeal scope, oral, pharyngeal, otorhinolaryngology
a supine position [6].

It is, therefore, necessary to observe the oropharynx with the patient in a sitting or standing posture while taking the pulse. However, the discovery of a lesion depends on the experience of the doctor, and thus, the differences in rates of discovery are large [8].

In children, careful pharyngeal observation is an important procedure for finding a foreign body [8], and is impossible without the voluntary participation of the child. Therefore, examination of the pharynx/oral cavity can be quite challenging as compared to that of the body trunk, limbs, ears, or nasal cavities. Forcing the mouth open with a device can be difficult because the masseter muscle is so strong that it requires considerable force. Moreover, the use of force can result in vomiting due to pharyngeal reflex and is a risk factor for tooth injury [9].

In addition, diseases in the pharynx and oral cavity are particularly difficult to diagnose and treat, not just in children or elderly patients. The display and recording of data during examination is generally indispensable for medical education and evaluation [10], but is currently lacking in clinical otolaryngology. To solve this problem, our study group developed a unique attachment with an integrated tongue depressor using HOYA Airway Scope (AWS), a video intubation device, with the AWS serving as a simple oropharyngeal endoscope (unpublished). The device was found to be useful in a study involving 10 doctors who examined 50 volunteers [11].

A follow-up study using an improved Type I device was conducted on a total of 150 people at 7 institutions including the National Hospital Organization Tokyo Medical Center, the Nagoya Medical Center, the University of Tokyo, Tokyo Medical and Dental University, Kyoto Prefectural University of Medicine and Jichi Medical University. The clinical utility of the device was noted in that study, and the effectiveness of pharyngeal endoscopy for the diagnosis of an aberrant (tortuosity change) internal carotid artery in the oropharynx was reported [12].

We then went on to develop an improved Type II device, and the present study protocol was designed to evaluate its utility and application as an oropharyngeal endoscope.

**METHODS**

Outline of the investigational device

An oropharyngeal endoscope with integrated tongue depressor is composed of a body part for displaying an image and a blade part. Based on the HOYA AWS, we improved and further downsized the type I device, the usefulness of which was verified in the previous study [12]. In order to facilitate treatment using an oropharyngoscope, we improved the placement of the monitor so that the TV monitor and the actual observation point are directly aligned. In addition, we have made Type II smaller and lighter. We also developed a more suitable blade (Table 1), which is removable and can be adjusted for various age groups. In this study, we will use the improved type II (Figure 1), whose lighter weight and smaller detachable blade allow it to be used in a wide range of age groups. It has the following applications: 1. oral cavity/pharynx observation, 2. suction of secretion, 3. carotid artery echo for finding risk factors of cerebral infarction, 4. airway management (tracheal intubation), 5. confirmation of insertion of a stomach tube.

| Bladder scheduled to be developed | Main character |
|----------------------------------|----------------|
| Observation of the oropharynx    | This is a blade shaped like a tongue depressor for observation of the oral cavity and pharynx. Examination can be performed just by holding the blade between patient’s teeth, with no reflection. |
| For suction of secretion         | Currently, suction of secretion is blindly performed. However, by using this blade, it can be performed accurately under observation. |
| Carotid artery echo for finding risk factors of cerebral infarction | It has a lumen that can induce carotid artery echo, and forceps insertion is also possible. |
| For tracheal intubation          | This blade was improved based on the conventional AWS. A qualified person can perform intubation regardless of experience. |
| Gastric tube insertion/observation | This blade ensures correct insertion of the stomach tube, and prevents incorrect insertion into the trachea. |
Study design

After acquisition of written consent, observation and treatment of the patient’s oropharynx was performed using the investigational device. After observation/treatment, the doctor, the display viewer, the patient, and their family will evaluate the efficacy of the device based on the criteria described in Table 2. The evaluation criteria involve rating specific attributes on a scale of 1 to 5, compared to conventional light sources and fiber or electronic scopes.

Endpoints

The primary endpoint is evaluation by the doctors who use the investigational device as an oral laryngoscope (evaluation items A to G, Table 2).

Secondary endpoints are to understand patient and family satisfaction (evaluation items H to J, Table 2) and display viewer satisfaction (doctors and other medical staff; evaluation item A to G, Table 2).

Sample size

The target number of enrolled patients is 100. Because this study only aims to evaluate the utility of the improved type II device and assess the need for further improvements, and because the number of devices is limited, sample size was determined based on feasibility rather than statistical analysis.

Statistical analysis

The number of patients enrolled in the study and who were observed using the investigational device will be considered an analysis set. The frequency dis-
distribution of the ratings of each evaluation item will be calculated. Age, gender, disease, treatment, the number of years of experience of the examining doctors and their department are summarized.

**DISCUSSION**

There is an increasing need to develop a readily available display method for use during oropharyngeal examination that (i) would be acceptable to patients, (ii) would be visible to third parties, and (iii) could be used by doctors for recording and treatment. However, except for one previous study [12], there are currently no devices that can record observations during an oropharyngeal examination. To solve this problem we developed a dedicated device (Improved Type I), which was evaluated in a previous study and potential improvements to this type I device were identified. The clinical utility of the device was established and no adverse events associated with the type I device were noted. Based on the observations from the previous study, we developed an improved Type II oropharyngeal endoscope. Based on the present study, we will further develop our new pharyngeal scope with the goal of making it available for use in daily practice.

**DECLARATION**

**Competing interests**

Authors declare no conflicts of interest.

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**Authors Contribution**

KT designed the study and prepared an implementation plan. AK refined the study design and statistical analysis. AS supported the creation of the protocol on data management. RK, YH, HM, KH, TC, MH, YM and OK are responsible for the implementation of this study at the participating institutions. All authors reviewed and approved the manuscript.

**Ethics approval and consent to participate**

This study was approved by the National Hospital Organization Tokyo Medical Center Research Ethics Committee on April 6th, 2016 (approval number: R15-137). This study was registered in the Clinical Trial Registry (UMIN-CTR) on December 29, 2016 (UMIN000025472).

Written informed consent was obtained from every participant in the study.

| Evaluation items | Evaluation |
|------------------|------------|
| **A. observation** | 1. Poor 2. Inferior 3. No change 4. Superior 5. Excellent |
| **B. treatment** | 1. Poor 2. Inferior 3. No change 4. Superior 5. Excellent |
| **C. recording** | 1. Poor 2. Inferior 3. No change 4. Superior 5. Excellent |
| **D. display** | 1. Poor 2. Inferior 3. No change 4. Superior 5. Excellent |
| **E. safety to use** | 1. Poor 2. Inferior 3. No change 4. Superior 5. Excellent |
| **F. convenience** | 1. Poor 2. Inferior 3. No change 4. Superior 5. Excellent |
| **G. possibility of future use** | 1. Never 2. Probably not 3. Yes, if available 4. Probably yes 5. Yes, definitely |

| Evaluation items | Evaluation |
|------------------|------------|
| **H. discomfort of examination** | 1. Felt discomfort 2. Slight discomfort 3. No change 4. Fairly comfortable 5. Comfortable |
| **I. anxiety of examination** | 1. Anxious 2. Slightly anxious 3. No change 4. Slightly relieved 5. Relieved |
| **J. recording/display explanation** | 1. Difficult to understand 2. Slightly difficult to understand 3. No change 4. Fairly easy to understand 5. Easy to understand |
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