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Development of Neonatal Airway Management Simulator for Evaluation of Tracheal Intubation

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***Abstract*— The long-term goal of this study is a training system that can simulate medical cases and advise physicians based on quantitative evaluation of neonatal resuscitation. In this paper, we designed and manufactured a neonatal airway management simulator for quantitative evaluation of tracheal intubation. This robotic simulator is equipped with 25 sensors of 6 types, which detect motions that lead to complications, inside the manikin replicated a neonate. A performance experiment of the developed sensor and an evaluation experiment with physicians were conducted. We observed that an erroneous operation in the laryngoscopy can be detected by the sensors in our simulator.**

I. Introduction

Currently, the shortage of doctors is a problem in pediatrics and emergency medical care, and the construction of a high-quality and efficient medical care provision system is an urgent issue [1]. In order to secure high-quality human resources, the field of medical education is shifting from a tour type to a participatory type, and simulation training is also becoming widespread [2]. Conventional simulation training can be broadly divided into a method using a simulated patient played by a healthy person and a method using a manikin simulator. Simulated patients are suitable for interview training but should not be applied for dangerous procedures. Therefore, invasive procedures including venous blood sampling and tracheal intubation are generally trained on a manikin simulator [2]. In addition, the manikin simulators are suitable for training neonatal resuscitation and laparoscopic surgery, which are difficult to have sufficient experience in clinical training, because physicians can repeatedly train under the same conditions. On the other hand, conventional manikin simulators have a little function of pointing out erroneous motions that can lead to complications. Therefore, feedback to trainers depends on the instructors. It is a constraint on ensuring the quality and opportunity of repeatable training. We have been working on case simulation and quantitative evaluation of the suturing and the adult airway management by applying robot technology to manikin simulators [3, 4].

In this study, we focused on neonatal resuscitation, which is particularly difficult for clinical training. We are developing a neonatal resuscitation training system that can simulate various case scenarios based on the guideline [5] and advise according to quantitative evaluations of their procedure. In this paper, we have designed and manufactured a neonatal airway management simulator equipped with various sensors for quantitative evaluation of tracheal intubation, which is one of the most dangerous neonatal resuscitation procedures. A performance experiment of the developed sensor and an evaluation experiment with physicians were conducted.

II. Neonatal Cardio-pulmonary Resuscitation

A. Overview

Tracheal intubation is a procedure in which a tube is inserted from the mouth or nose through the glottis to directly ventilate the lungs. The procedure for oral tracheal intubation is as follows [6]: First, the patient is made to take a supine position in which the nose sticks out, called the sniffing position. Second, a metal instrument called a laryngoscope is inserted through the mouth, and the tongue and epiglottis are lifted up (Fig. 1 (a)). This lifting technique is called laryngoscopy. Third, the tube is inserted through the glottis visually (Fig. 1 (b)). Finally, the laryngoscope is removed, and ventilation is performed with the tube.

B. Dangers Associated with Tracheal Intubation

The most notable erroneous operation in laryngoscopy is the "lever motion" with the maxilla as a fulcrum [6]. When lifting epiglottis, it should be moved in parallel with the direction of its handle. However, beginners often rotate the

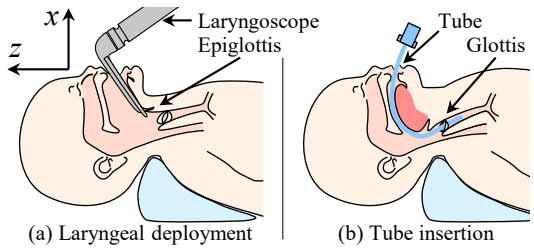

Figure 1. Tracheal intubation procedure

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laryngoscope like a crowbar with the maxilla as a fulcrum. In this case, a large pressure is applied to maxilla, which may damage the gingiva. It has been reported that pressure on the maxilla may cause the incomplete eruption of primary teeth [7]. Therefore, pressure on the maxilla should be avoided in neonates as well as in adults, although neonates don't have teeth. The lifting displacement of the laryngoscope is also important: Insufficient lift can cause erroneous intubation into the esophagus because the glottis cannot be seen. On the other hand, when the lifting force is too strong, it may cause a complication, a dislocation of the arytenoid cartilage around the glottis. Additionally, the insertion depth of the tube also should be attended because it relates to the ventilation efficiency. When the tip position of the tube is shallower than the glottis, the ventilation pressure does not reach the lungs. On the other hand, when it is too deep, the tube reaches either of the main bronchi, making it impossible to ventilate the lung of the other side. Furthermore, it is especially dangerous when the tube invades into the esophagus; not only ventilation is impossible, but also the contents in the stomach may regurgitate and flow into the lungs.

Tracheal intubation is the most reliable method for a skilled doctor to open the airway, but the improper operation can cause complications. However, tracheal intubation should not take more than 20 seconds [5] even if it is conducted without complications. The delay can cause oxygen shortage and increase death risk. Therefore, we evaluated the physician's skill based on improper operations with excess and insufficiency in this study.

III. Neonatal Airway Management Simulator

A. Overview

Fig. 2 shows the neonatal airway management simulator which we designed and manufactured. Sensors that detect erroneous operations were installed in 25 points of 6 types inside the simulator, and the measurement data is wirelessly transmitted to the procedure evaluation computer online. In addition, this simulator was designed based on the average body of healthy neonates (Table 1), and we aimed to create a simulator that looks like a neonate by using flexible parts inside and outside the body. This simulator was manufactured based on the manikin (Kyotokagaku, Japan), the frames of the head and body were newly designed with SOLIDWORKS and 3D printed using CONNEX Objet500 (Stratasys, Israel).

B. Procedure Measurement Sensors

1) Head and Body Posture Sensors: Two LPMS-B (LP-Research, Japan,) 9-axis IMU with built-in Bluetooth is mounted to measure the postures of the head and body. They were utilized to detect the complications containing cervical hyperextension and insufficient back bending when the neonate is made to take the sniffing position. They were fixed to the top of the head and the lower abdomen. The neck angle was calculated by the difference between the two pitch postures obtained from the IMUs. We are also planning to measure postures around the roll and yaw axis and the impacts during the procedure in the future.

2) Oral Camera: MCAM-AMIR-WTF-HD (Broadwatch, Japan,) an infrared camera was mounted in the head to shoot the oral cavity. This camera with a battery in a 60 x 20 x 20 [mm] housing can shoot videos with a maximum resolution of 640 x 480 pixels from visible to near-infrared rays, and broadcast images to a computer using a Wi-Fi transmitter. In this study, this camera was combined with a commercial 12x macro lens and shoot around the epiglottis from the nasopharynx. In addition, the oral cavity was illuminated using an infrared LED array so that physicians don't sense the light. The position where the blade of the laryngoscope presses is important in laryngoscopy, but it is difficult for trainers and supporters other than the operator to see in the oral cavity of a conventional simulator. We aimed to utilize this camera for visual evaluation similar to video laryngoscopes. In this study, since this simulator didn't assume nasal intubation, it will be necessary to relocate the oral camera when adding a nasal cavity.

3) Laryngeal Pressure Sensors: Regarding the force lifting larynx in laryngoscopy, training is currently assessed only based on the qualitative indicator of "protectiveness", which is not clear on the risk. Therefore, we have designed and implemented a novel compact and flexible pressure sensor array on the larynx to evaluate the laryngoscopy based on the pressure distribution. Fig. 4 shows the *mechanism* measuring the pressure on a point. This sensor consists of a sponge containing bubbles, an infrared LED, and a phototransistor. The amount of infrared transmission of the

TABLE I. Body Specifications

	Developed simulator	**Healthy neonate [8]**
Height	520	500
Weight	2600	2500 – 3500
Head circumference	325	330

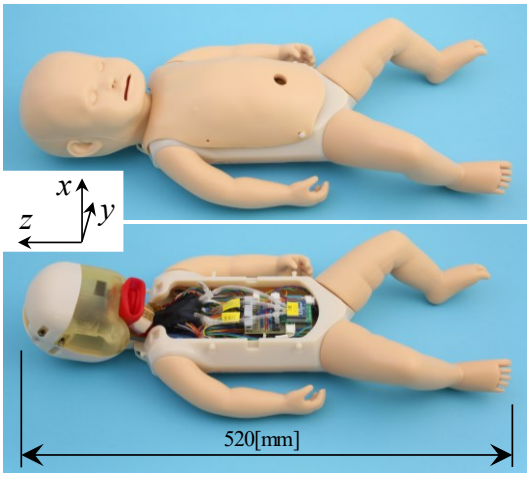

Figure 2. Appearance and interior of neonate airway management simulator

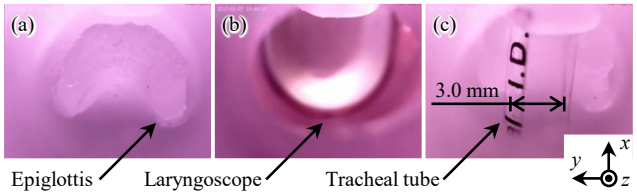

Figure 3. Captured images of oral camera
(a) Before laryngoscopy (b) During laryngoscopy (c) Tracheal intubation

sponge compressed by pressure was measured using the pair of infrared LED and phototransistor. In this study, the sponge was made of synthetic rubber for cosmetic puffs with a thickness of 5 [mm], and QRE1113GR (Fairchild, USA), a small photosensor, in which an infrared LED and a phototransistor were packaged, was mounted on the flexible circuit substrate so that we could realize an inexpensive sensor. To detect the point touched by the laryngoscope according to the pressure distribution, the sensor sets were arranged on six points; both sides of the head side, the tail side, and the above of the epiglottis.

4) Maxillary Pressure Sensor: FSR-400 (Interlink Electronics, USA), a film-like pressure sensor was inserted between the parts corresponding to the skull and gingiva to measure the pressure on the maxilla by the "lever motion" in laryngoscopy. This sensor changes the resistance according to pressure, and we measured the resistance using a simple voltage divider.

5) Tube Position Sensor: Six pairs of RPR-220 (ROHM, Japan), infrared photo-interrupter were arranged at one point of the esophagus and five points on the trachea from the behind glottis to the front of the bronchi to evaluate the tip position of the tracheal tube. The infrared rays of each pair intersected at the central axis of the trachea so that the sensors can detect the passage of the neonatal tube with the outer diameter of 6 [mm] floating in the trachea with the inner diameter of 10 [mm]. The tracheal tube for neonates does not always pass the central axis because it does not have a cuff, a balloon sealing the airway and fixing the tube inside the trachea, like those for adults. The sensor spacing from the glottis to the bronchi was set to 5 [mm], referring to the clinical standard for adjusting the depth of intubation [6].

6) Ventilation Pressure Sensors: Three MIS-2500-015G (Metrodyne Microsystem, Taiwan), gauge pressure sensors were connected to both lungs and stomach to detect the insufficient operations; one-lung ventilation and air inflow into the esophagus. Additionally, the balloons, which expand responding to ventilation, were connected to the bronchi for simulating visual assessment.

C. Control system

Nucleo-144 STM32F746 (STMicroelectronics, Switzerland), a microcontroller was embedded for A/D conversion of sensor outputs and control of LEDs, and two XB24-Z7PIT (Digi International, USA), ZigBee wireless modules were utilized for wireless communication with VAIO SVF152A16N (SONY, Japan), a laptop for procedure evaluation. In addition, the IMUs and camera communicated with the laptop using the built-in Bluetooth and Wi-Fi module.

IV. Experiments and Discussions

A. Performance Experiment of Laryngeal Pressure Sensors

We conducted an experiment of laryngeal pressure sensors manufactured in this study to verify the ability to detect insufficient and excessive lifting in laryngoscopy. The experimental method is as follows:

1. The output voltages V_o [V] of the six laryngeal pressure sensors shown in Fig. 5 were recorded at the initial condition.
2. Larynx in the simulator was lifted up as high as "(A) the whole glottis was visible" from the operator.
3. The mean voltages V_{out} [V] were recorded during the lifts.
4. Similar to steps from 1 to 3, V_o and V_{out} were recorded at two conditions; "(B) only half glottis was visible" and "(C) glottis was not visible".
5. Steps from 1 to 4 were repeated six times.

In this experiment, the sensor outputs were compared using the percentage P_i in the following equation. The reference potential for A/D conversion is 3.3 [V].

$$P_i = \frac{V_{out}-V_o}{3.3-V_o} \times 100\ [\%]$$

The experimental results are shown in Fig. 6. At each measurement position of L1 to L3 and R1 to R3, proportional relationships were observed between the lift amount (A, B, and C) and the output P_i, and significant differences ($p < 0.01$) in the student t-test with Bonferroni correction were confirmed under all conditions.

In this experiment, we set condition (A) as excessive lift and condition (C) as insufficient lift because the visibility of the glottis affects the success of intubation. However, the exact allowable range of the lift amount has not been clarified yet, so further study is required. From this result, it was observed the possibility of the simulator detecting these erroneous operations. Looking at Fig. 6, the output of L2 and R2 is larger than the output of other measurement positions at each lift. This is because the tip of the laryngoscope at the time of the experiment is located at the parts of L2 and R2. From this, it

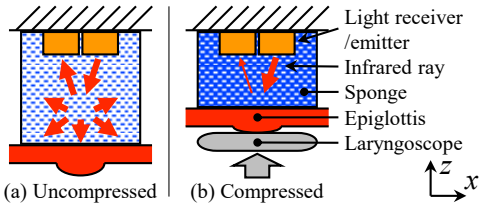

Figure 4. Principle of laryngeal pressure sensor

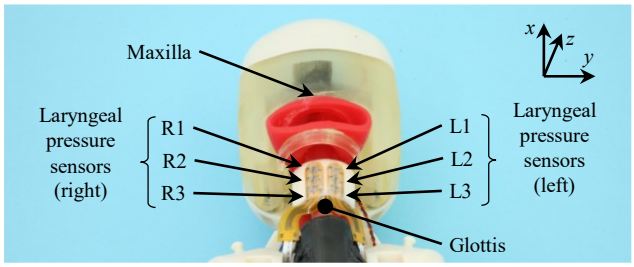

Figure 5. Measurement position of laryngeal pressure sensor

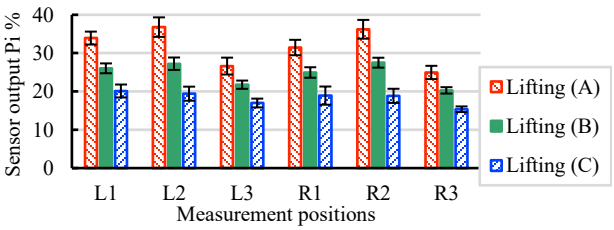

Figure 6. Laryngeal pressure sensor output for each lift

may be possible to estimate the position of the laryngoscope from the position and output ratio of each laryngeal pressure sensor. This can be verified using the position information of the laryngoscope obtained by the oral camera, and we would like to verify it in the future.

B. Evaluation Experiment by Doctors

In order to verify whether the skill of doctors can be evaluated using this machine and to identify problems in using it in training, a demonstration experiment was conducted with the cooperation of doctors. The Waseda University's Ethical Review Board approved all experimental procedures involving human subjects. (No. 2014-229)

The subjects were 6 neonatologists, 4 pediatricians, and 4 obstetricians at the National Center for Child Health and Development. The number of experiences of neonatal tracheal intubation was 5 to 100 times for neonatologists, 1 to 5 times for pediatricians, and 0 to 20 times for obstetricians, respectively. In the experiment, each doctor performed one neonatal tracheal intubation on this machine as in clinical practice and recorded the sensor output at that time. Two assistants assisted the procedure in order to maintain the posture of the patient (this machine) and hand over the laryngoscope. In addition, we conducted an interview survey on this machine after the measurement was completed.

First, Fig. 7 shows a typical example of laryngeal pressure during a skilled doctor's procedure. Looking at one point of the laryngeal pressure sensor and the time change of the upper jaw pressure sensor as a sensor related to "laryngeal operation", which is one of the erroneous operations, the laryngeal pressure rises from t = 16 to 30 [s]. This corresponds to the stages of laryngoscope insertion, laryngeal deployment, and tube insertion. After removing the laryngoscope, it returned to the initial value. On the other hand, the maxillary pressure temporarily increased at the time of insertion and removal of the laryngoscope, but showed a low value during elevation. It is considered that this is because the skilled doctor performed the procedure so that the laryngoscope did not touch the upper jaw during laryngeal deployment so as not to perform "lever operation".

Next, as a skill evaluation focusing on this "lever operation", the maxillary pressure was compared between a neonatologist who had a lot of experience and another doctor who had a relatively small experience. Fig. 8 shows a comparison of the maximum maxillary pressure during the procedure. It was confirmed that the neonatologist, who has a lot of experience and is considered to be skilled, has a significantly smaller maxillary load than others ($p < 0.01$) and can perform quantitative skill evaluation focusing on "lever operation".

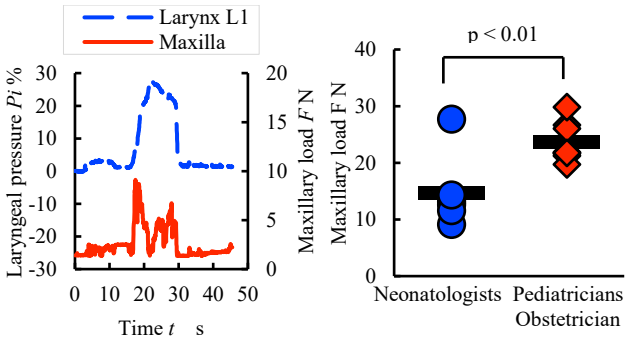

Figure 7. Skilled doctor's procedure measurement result

Figure 8. Comparison by load on the upper jaw

This study has limitations. In this experiment, the subjects did not include any anesthesiologists, who are experts of tracheal intubation for adults and used to larger instruments than one for neonates. We would like to compare the pressures on the larynx and the maxillary by anesthesiologists to neonatologists using the manufactured simulator. Additionally, the subjects were from the same hospital. The customs and educations of each hospital may affect the experimental results.

V. Conclusion

We have developed a neonatal airway management simulator that quantitatively evaluates the tracheal intubation procedure included in the neonatal resuscitation method, with the aim of developing a training system that can repeatedly perform neonatal resuscitation methods that are difficult to clinically train. This machine has an appearance similar to that of a neonate baby and has a large number of sensors and can detect erroneous operations that cause complications. We conducted an experiment to detect the amount of epiglottis elevation and confirmed its effectiveness. In addition, an evaluation experiment was conducted by doctors, and problems were identified by hearing.

In the future, in addition to improving the above-mentioned problems, we plan to install a function to reproduce the condition of the patient in order to support training for the entire guideline. In addition, after repeating more measurements, we will examine the quantitative evaluation and advice presentation function of the entire procedure.

References

[1] S. Konuma, "Current status and issues of pediatric medical policy in Japan and major countries", *Measures for Declining Birthrate and Aging Population*. Tokyo: National Diet Library, pp. 59-73, 2005 (in Japanese).

[2] K. Ishikawa, A. Sugawara, G. Kobayashi, and N. Nara, "A 2012 nationwide survey on the application of simulation-based education in medical schools in Japan", *Medical Education Japan*, vol. 44, no. 5, pp. 311-314, 2013.

[3] J. Solis, N. Oshima, H. Ishii, N. Matsuoka, K. Hatake, and A. Takanishi, "Towards understanding the suture/ligature skills during the training process using WKS-2RII", *International Journal of Computer Assisted Radiology and Surgery*, vol. 3, pp. 231-239, 2008.

[4] Y. Noh, C. Wang, M. Tokumoto, Y. Matsuoka, T. Chihara, H. Ishii, A. Takanishi, T. Takayama, and S. Shoji, "Development of the Airway Management Training System WKA-5: Improvement of Mechanical Designs for High-Fidelity Patient Simulation", *IEEE International Conference on Robotics and Biomimetics (ROBIO)*, 2012, pp. 1224-1229.

[5] S. Hosono, M. Tamura, T. Isayama, T. Sugiura, I. Kusakawa, and S. Ibara, "Summary of Japanese Neonatal Cardiopulmonary Resuscitation Guidelines 2015", *Pediatrics International*, vol. 62, issue 2, pp. 128-139, 2020.

[6] B. Aehlert, *PALS Pediatric Advanced Life Support Study Guide, Third Edition* (K. Miyasaka, Trans.), Tokyo: Elsevier Japan, 2013.

[7] Y. Matsuzaki, Y. Uchikawa, H. Hoshiyama, Y. Niimi, and T. Shirase, "Incomplete Eruption of Maxillary Primary Anterior Teeth Possibly Caused by Tracheal Intubation", *The Japanese Journal of Pediatric Dentistry*, vol. 53, issue 1, pp. 81-81, 2015.

[8] Y. Hatae, R. Kobayashi, M. Nishi, *STEP Pediatrics, Third Edition*, Tokyo: Kaibashobo, 2015 (in Japanese).