Study on Patient Simulation Robots for Airway Management Training

気管挿管手技訓練用患者ロボットに関する研究

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To my dear family and my friends

ACKNOWLEDGMENTS

"Shoot for the moon. Even if you miss

you will land among the stars."

Les Brown, Sr. (March 14, 1912 - January 4, 2001)

This research had been performed from 2006 to 2008 which was supported by Knowledge Cluster Initiative, and a project from the Ministry of Education, Culture, Sports, Science and Technology of Japan, and since 2009, this research has been performed by Kyotokagaku Co. Ltd. Without supporting lots of finance, the author has never performed this research. The author would like to express special gratitude to Waseda University. The author also would like to express gratitude to WABOT HOUSE in Gifu Prefecture and to SolidWorks Japan K.K for their support. In addition, these projects have been colaboratted with many doctors because they are related with medical science, and also need to know knowleadge of medical science. During performing the experiments, many doctors who were involved in the department of Anesthesiology, Tokyo Women's Medical University participated in our experiments, and they gave us valuable information. Particularly, the author would like to apprecieate on Higuchi Prof., Takaki Prof., Kuruma Prof., and Nagai Prof. Moreover, the author also would like to appricate on Onishi Prof. who also prvided valuable information on human anatomy.

In 2006, and in 2007, for the this research, Fujimoto Prof. who is an medical doctor and a professor in Waseda University helped us to perform the experiments and gave not only variable advice, but also have a tough time deciding on my personal works. Moreover, Prof. Fujimoto, Umedu Prof., and Fujie Prof. helped and instructed how to edit and organize my thesis. Not only the instruction but also the conversation was good chance for me to improve my scientific knowledge and my life knowledge. The author would like to appreciate on them again. After my graduation, the author will try to learn medical science in the United States to be a good scientist in the field of the Biomedical Engineering.

In the takanishi Laboratory, the author would like to appreciate on Ishii, Solis, and Secretary Ohta, and Itoh, and my colleage: Nagahoro, Shimomura, Kikuta, Sato, Ebihara, Shoji, Segawa, Tokumoto, and all of members of Takanishi Lab. Without the support from them, the author never could research, and complete these good achievements. In 2009, the author might be expelled from Waseda University because the author did not tuition to the university, at that time, Umedu Prof., Fujie Prof., Hashimoto Porf., and Others who were involved in the deparment of the advanced mechanical engineering, Waseda University helped me not to expel from the university. The author also would like to appreciate on Umedu Prof., Fujie Prof., and Others.

In order to complete this project, the author would like to appreciate on Shoji who is a member of Kyotokagaku Co., Ltd. Without his passionate enthusiasm for this project, the author will not complete it. The author had good memories with Shoji that we researched and exchanged our opinion on our project during every night in Waseda and in Kyoto Kyotokagaku Co., Ltd.

For my graduation, many of my friends who are living in Sakura House or in Korea have cheered for me. The author has been in Sakura house for 6 years, and the author has learned many languages such as Italian, Chinese, English, German, and French. In addition, the author could have chance to experience foreign culture exchange, and have written a novel, "Legend of Sakura house for 6 years". It will be released in Korea next year 2012.

I would like to appreciate on Secretary Ohta, and Itoh who have supported a lot of things. The author has been always trouble in the Lab., but thanks to their warmness, and their supporting, the author has repented of my wrongdoings, and could overcome every life in Japan. Particularly, I would like to appreciate on Ohta, and Itoh about the SI 2010 Conference trouble. With their love and supporting, the author could get an award in SI 2010 Conference.

6 years ago, when the author came to Takanishi Lab, the author would like to join in the Biped Group. Although Ohta told me many time that Intellectual Cluster Group is much better than the Biped Group cause it has a lot of finance sponsored by Japanese Governement, and its goal is for the commercialization. Now, the author is feeling ignorance, and Ohta's

advice was right. Thanks to Ohta's advices, the author could achieve many achievements such as papers, patents, and awards. The author would like to say that it was impressive that among those achievements, the author could have experiences of the commercialization for our robor. This will help me what to do in the future.

Finally, the author would like to appreciate on Takanishi Prof. He have tought me not only knowledge of robotics but also life. When the author watched Korean News in 2004, the author made a decision to go to Japan to learn Robotics not in the United States. Takanishi Prof. was my hero, and that is why the author came to Waseda University. In the future, my life will have been with his spirite of his robotics physiology.

ABSTRACT

Simulations are often used in the training of civilian and military personnel when it is prohibitively expensive or dangerous to allow trainees to use actual equipment in real world conditions. In such situations, simulations allow trainees to learn valuable lessons in a safe, "virtual" environment. One common convenience of this system is that mistakes are allowed in systems where safety is normally a critical issue. Simulations used in education are somewhat like training simulations in that they focus on specific tasks. In this thesis, the author focuses on the simulation of medical tasks.

In clinical medical fields, doctors constantly face a variety of patient situations, situations in which medical accidents are a possibility. Medical training is the best countermeasure for such accidents, but the best training methods require human volunteers, which presents far too many risks and ethical problems. This is why medical doctors and students employ several types of medical training simulators, but most existing models only have a few sensors attached to their systems, providing little quantitative information to the trainee and forcing instructors to provide subjective assessments. In addition, they do not simulate the real-world conditions of the tasks they simulate. As an alternative, the author proposes an innovative training system using Robot Technology (RT), with a high number of embedded sensors, actuators, and evaluation units within the training system.

This innovative, RT-based training system is introduced as a way to provide more effective training. At the minimum, an innovative training system must fulfill three specific conditions: it must 1) provide useful feedback to trainees and objective assessments of training progress, 2) reproduce the various patient patterns, 3) reproduce Patient Scenario for

real-world conditions of the task and adjust degree of difficulty for trainee's effective training, and 4) simulate high-fidelity simulated human anatomy.

In this thesis, the author presents an airway management training system which fulfills the three requirements stated above for an effective, innovative training system. Airway management is a basic skill provided during emergency situations such as cardiopulmonary arrest. It clears the airway, ensuring that air can reach the lungs, and prevents the entry of gastric juices or blood. There are currently many kinds of the airway management training simulators, developed by a range of companies. Some high cost simulators have functions which enable trainees to train not only airway management, but also general anesthesiology and various other medical tasks. In contrast, low cost simulators only allow training in airway management. But neither type of conventional system can fulfill the requirements for an effective, innovative training system.

Conventional systems have a small number of sensors, and provide little quantitative information to the trainee. They rely on instructors, normally professional doctors, for subjective assessment of trainee performance. For these reasons, it is preferable for trainees working with conventional systems to receive instructor guidance during the training sessions and during practice sessions with human volunteers. The expenses for the training and practice sessions are therefore proportional to the number of trainees. However, the proposed innovative training system can provide a great deal of quantitative information on trainee performance, which can be used to give objective assessment without the instructors. Trainees will still gain a better understating of their performance when instructors are present, but with the proposed system, the author expects only a few instructors will need to be present during the training and practice sessions. Consequently, the author expects that the expenses for the training and practice sessions will be smaller in relation to the number of trainees than with conventional simulators, effectively reducing total expenses. Furthermore, the author also expects that our proposed training system will provide a more effective training experience than the conventional systems.

For these reasons, in this thesis, the author proposes an airway management training system by applying the concept of the innovative training system which fulfills the four requirements stated above, and establishes a design methodology for the development of the innovative training system for the airway management. In order to establish the design methodology for the innovative training system for the airway management, the author has plans to develop each of the training system which fulfills one of the requirements for an effective, innovative training system, and finally, the author has a plan to integrate each of the systems into the one system. For the purpose of these facts, the author presents the development details of the innovative airway management training system, presents each of the WKA series, and establishes the design methodology for the development of the innovative training system for the airway management.

In the chapter one, the author introduces general simulation systems and the simulation systems used in training and education, focusing on simulations for medical training. The author also proposes the general concept of the innovative training system in comparison with conventional training systems, and states the purpose of this research.

In the chapter two, the author establishes a way to provide quantitative information of the trainee's performance of the tasks to trainee while performing airway management, and provide objective assessment. For the purpose of these facts, the author presents the WKA-1R which has embedded sensor systems to obtain quantitative information of trainee's performance. There is a variety of such sensors, such as Force Detection Sensor Systems (FDSS), Position Detection Sensor Systems (PDSS) and Displacement Detection Sensor Systems (DDSS). The data collected is integrated into an evaluation function that provides a quantitative assessment of a trainees' skill. The experimental results show that the WKA-1R is able to quantitatively detect the differences in expertise among participants with a range of skill levels (unskilled trainees, medical students and anesthetists).

In the chapter three, the author establishes a way to reproduce the various patient patterns by reproducing various airway difficulties and individual airway difficulties and by simulating stiffness of the human muscle. For the accomplishment of these, the author presents the WKA-2 which consists of a wire driving mechanism containing 16 embedded actuators and 16 embedded Tension/Compression Detection Sensor Systems (TCDSS). From the results of the experiments using the WKA-2, the author confirms the relationship between the shape of the oral cavity, the mandible, the tongue, and the angle of the head which makes airway management difficult by reproducing various patient patterns such as airway difficulties, and individual differences. In addition, the author verifies the effectiveness of the control system for the simulation of the human's muscles.

In the chapter four, the author establishes a way to reproduce the *Patient Scenario Generation* for the real world condition of the tasks and adjust degree of difficulty for trainee's effective training. It can reproduce not only static or time-invariant patient characteristics, but also of dynamic or time-variant ones. For the purpose of these facts, the author proposes the WKA-3 which has 6 embedded actuators and 52 embedded sensors. This training system is expected to fulfill the three requirements for an effective innovative training system. To do so, the WKA-3 not only integrates the functions of WKA-1R and WKA-2, but also improves system mechanism performance. Finally, the author discusses the results of a set of experiments carried out to verify the effectiveness of the proposed Patient Scenario Generation, using doctors and students as subjects.

In the chapter five, the author establishes the methodology of the innovative training system for the airway management. Although the WKA-3 fulfills the three requirements for an innovative training system, it does not consider external appearance such as the "patient's" skin, and internal appearance such as the pharynx, larynx, and esophagus. Moreover, the tongue mechanism of the previous system cannot measure precisely the applied force by the medical device and cannot simulate stiffness of the human's muscle. In addition, the mandible mechanism and the neck mechanism of the previous system also have deficiency in reproducing the various cases of airway difficulties and in applying force control. For these reasons, the author proposes WKA-4, which has high-fidelity simulated human anatomy, and satisfies all of the requirements for the effective, innovative training system. In this chapter, the author presents the WKA-4 which has 11 embedded actuators and 44 embedded sensors, and improved the internal and external anatomical appearance over the WKA-3. From the result of the experiment, the author confirms that the WKA-4 simulates the motions of the neck, the tongue, and the head of the real human more closely than the ones of the conventional training system. Moreover, the author also confirms that the one group with the score feedback has the training effectiveness than another group without the score feedback information through the learning curve. Therefore, the author verifies that the proposed innovative training system has better training effectiveness than the conventional training system.

In the chapter six, the author presents the conclusion and discusses future works, such as the possibility of using the proposed innovative medical training system in the other fields of medical training, and presents the possibility of the commercialization.

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LIST OF ABBREVIATIONS

LCMS	Low Cost Medical Simulators
HCMS	High Cost Medical Simulators
ITS	Innovative Training System
WKA-1R	Waseda KyotoKagaku Airway No.1 Refined
WKA-2	Waseda KyotoKagaku Airway No.2
WKA-3	Waseda KyotoKagaku Airway No.3
WKA-4	Waseda KyotoKagaku Airway No.4
WKA-5	Waseda KyotoKagaku Airway No.5
FDSS	Force Detection Sensor System
PDSS	Position Detection Sensor System
DDSS	Displacement Detection Sensor System
TDSS	Tectile Detection Sensor System
GUI	Graphic User Interface
PI	Performance Index
InT	Intubation Index
JaO	Jaw Openig
InF	Incisor Teeth's Force
ToF	Tongue's Force Index
CPr	Cuff's Pressure Index
TuP	Tube's Position
AMTS	Airway Management Training System
TCDSS	Tension Compression Detection Sensor System

DI	Displacement Index
MCU	Micro Controller Unit
ADC	Analog Digital Converter
VFSS	Video Fluorographic Swallowing Study
SBME	Simulator-Based Medical Education
GAS	Gainesville Aesthesia Simulator
CASE	Comprehensive Anaesthesia Simulation Environment
METI	Medical Education Technologies, Inc.
IDS	Intubation Difficulty Scale
ACRM	Anaesthesia Crisis Resource Management

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Chapter 1

Introduction

1.1 Background

1.1.1 Importance of Medical Training

In Japan, every year the medical accidents have been reprorted. Without a lot of experiences, Novices may be trouble with their medication to the patients. This sometimes may lead to the medical accidents. Regardless of these medical accidents, patients did not be afftected, but in the worst case, the patients lead to be in the critical state. For the prevention of the medical accidents, medical training has been performed in the medical fields. Medical training must at some point use live patients to hone the skills of health professionals. At the same time, there is an obligation to provide optimal treatment and to insure patients' safety and well-being. These conflicting needs create a fundamental ethical tension in medical education, one that is widely recognized although little discussed. Recent articles in the bioethical literature have condemned the unreflective use of patients—especially sedated or dying patients—as training tools for clinicians as shown in Fig. 1.1 [1][2][3][4].

Patients have the right to receive the best care that can be reasonably provided. It is understood that physicians-intraining will treat patients. However, from an ethical perspective, harm to patients as a byproduct of training or lack of experience is justified only after maximizing approaches that do not put patients at risk.The clinical encounter in a teaching

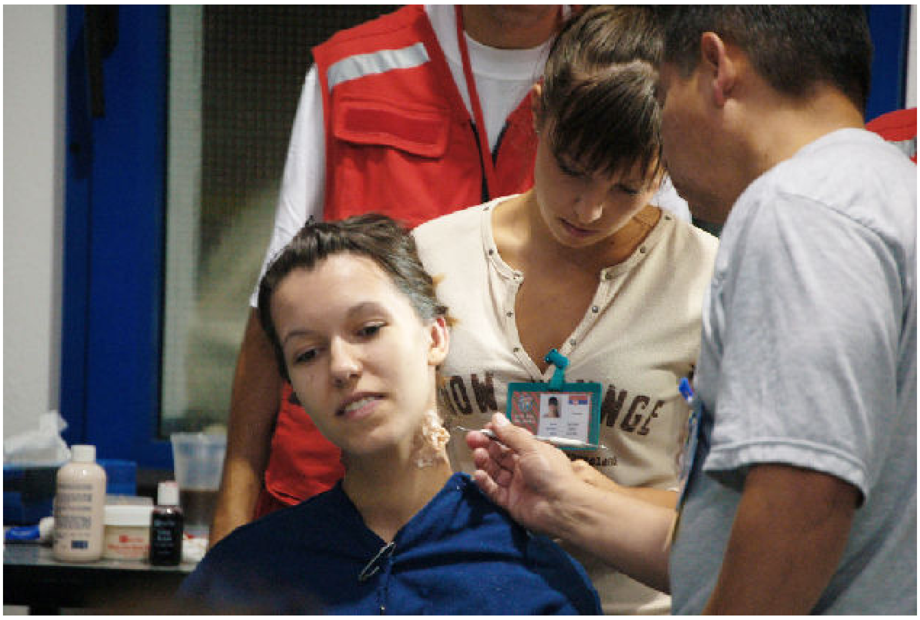


Figure 1.1 Medical training with volunteers

Figure 1.2 Medical training with simulator

environment may focus too much on training, at times to the detriment of the patient. Although instructors monitor trainees and patients during procedural and cognitive tasks, strategies to place patient well-being foremost occasionally fail. Novices experience significant performance anxiety, generally cannot focus on multiple tasks, and follow simple rules inflexibly [5]. Therefore, recently, in the medical field, emergent medical technicians

Figure 1.3 Medical training with simulator

and medical science students have performed Simualator-Based Medical Education (SBME). SBME allows trainees to more often have their first encounters with real patients when they are at higher levels of technical and clinical proficiency. Practitioners can use SBME to improve proficiency when learning new procedures or when honing existing skills. The use of simulation wherever feasible also can convey a critical educational and ethical message to all stakeholders in health care: patients are to be protected whenever possible and they are not commodities to be used as conveniences of training (Figure 1.2-1.3).

1.1.2 History of Clinical Simulation

Simulation has been defined as: The technique of imitating the behaviour of some situation or process (whether economic, military, mechanical, etc.) by means of a suitably analogous situation or apparatus, especially for the purpose of study or personnel training [9] Within this definition is included a large range of activities that are rightly regarded as being a part of the spectrum of clinical simulation. Simulation, in its many guises, is now widespread in many fields of human endeavour. The history of simulation stretches back over centuries. The military has been a longterm user of simulation: chess probably represents one of the earliest attempts at war gaming; jousting permitted knights to hone battlefield skills, and the 18th century Kriegspeil represented a development with more face validity, which has led to modern, complex, computerized warfare simulations. The modern aviation industry has developed high-fidelity flight simulation [6] and has led on improving the non-technical skills

Figure 1.4 Flight aviation simulators

Figure 1.5 Flight aviation simulators

of teams through crew resource management programmes (Figure 1.4-1.5). Similarly, the space programme has made extensive use of simulation for training and testing. The nuclear power industry, with its adverse experience of how bad things can be when they go wrong, such as at Three Mile Island and Chernobyl, is another business with a major commitment to simulation. What these groups have in common is that, for each of them, training or systems testing in the real world would be too costly or too dangerous to undertake. It is not surprising therefore that the medical profession should take steps to adopt the principles of highreliability organisations. Indeed, what may be more surprising is how long it has taken to get here. Clinical simulation does, in fact, span the centuries; for example, models have long been used to help students learn about anatomical structures. The modern era of medical simulation has its origins in the second half of the 20th century. Three distinct movements can be identified that have spurred the development of clinical simulation. The first, which occurred slightly earlier than the high-fidelity simulation developments and at the near opposite end of the spectrum, concerns the work of Asmund Lærdal. This cannot be underestimated in terms of its importance to the field and to humanity itself. Working with anaesthetists, Lærdal, a Norwegian publisher and toy manufacturer, developed the 'Resusci-Anne', the part-task trainer that was to revolutionise resuscitation training through the widespread availability of a low-cost, effective training model [7]. Since then, such simulation has evolved steadily, with an increasingly sophisticated range of manikins and models used in support of resuscitation and basic skills training becoming available (Figure 1.6). The second movement is quintessentially associated with modern simulation and concerns the development of sophisticated simulators dedicated to the reproduction of aspects of the human patient. The earliest of these was the Sim One, developed by Abrahamson and Denson in the late 1960s [8]. The manikin had a number of sophisticated features: 'It breathes; has a heart beat, temporal and carotid pulse (all synchronised), and blood pressure; opens and closes its mouth; blinks its eyes; and responds to four intravenously administered drugs and two gases (oxygen and nitrous oxide) administered through mask or tube. The physiologic responses to what is done to him are in real time and occur ''automatically'' as part of a computer program [9]. However, the Sim One failed to achieve acceptance, despite promising early reports of its effectiveness in training. This was largely because the need for anything other than apprenticeship-based training had not yet been defined and, secondly, because the cost of the technology at the time did not permit more than one example to be produced. In

Figure 1.6 Patient simulators (Laerdal)

Figure 1.7 Patient simulators (METI)

the 1980s, the feasibility of producing high-fidelity simulators was resurrected by two groups, the first at Stanford University and the other at the University of Florida. The former group, led by David Gaba, developed the comprehensive anaesthesia simulation environment (CASE) [10] and the latter, led by Michael Good and JS Gravenstein, developed the Gainesville anaesthesia simulator (GAS) [11]. The CASE was later to be commercialized as Medsim and the GAS eventually became the Medical Education Technologies, Inc. (METI) (Figure 1.7). The Stanford team focused significant attention on the development of team-based working in realistic simulation environments and incorporated the aviation model of crew resource management into the anaesthesia crisis resource management (ACRM) curriculum, leading to significant developments in clinical team-based training [12]. These simulators and some European counterparts (from Holland, Denmark and the UK) form or have formed the basis for today's modern moderate to high-fidelity simulator. They have been at the forefront of the development of high-fidelity simulation; led by the anaesthesia community these manikins have been central to the understanding and development of simulation-based learning and training to date. The third major movement has been that of medical education reform, which, in the latter part of the century, began an ongoing process that continues today. Some of this change has been driven by worldwide recognition of the need for students to be prepared as effective junior doctors after their undergraduate education [13][14][15][16]. The recognition of information overload within the undergraduate curriculum, at the expense of the learning of clinical and communication skills, has seen the widespread adoption of programmes in clinical skills learning and the development of clinical skills education facilities to support that learning [17][18][19]. Changes to postgraduate training have also come about as the need to adopt a sounder educational approach, coupled with a more streamlined process, has emerged. The need for continuing medical education after higher specialist training and the drive to revalidation has also been a significant part of this process. This has seen a rise in the use of simulator methodologies in both undergraduate and postgraduate education. Although much of this learning is at the lower end of the simulation spectrum, increasing attention is being paid to high-fidelity simulation as a means of providing safe, protected, educationally sound experience to undergraduate students, postgraduate trainees and established practitioners. Indeed, it has been argued that these changes are long overdue and that they represent an essential element of an ethically cognizant education [20].

1.2 Motivation of This Study

1.2.1 Convential Training System

In general, while training any kind of task, two main approaches can be conceived [21][22]: conventinal training system and innovative training system. Conventional training system is based on the idea of simulating with high fidelity the real-world conditions of the task (i.e. conventional mannequins); but without acquiring any information of the task performance. Thus, the amount of feedback information that can be provided to the trainee is considerably limited [23]. Although some training patient simulators can generate performance data [24], often, there is no one correct response to an adverse event [25],

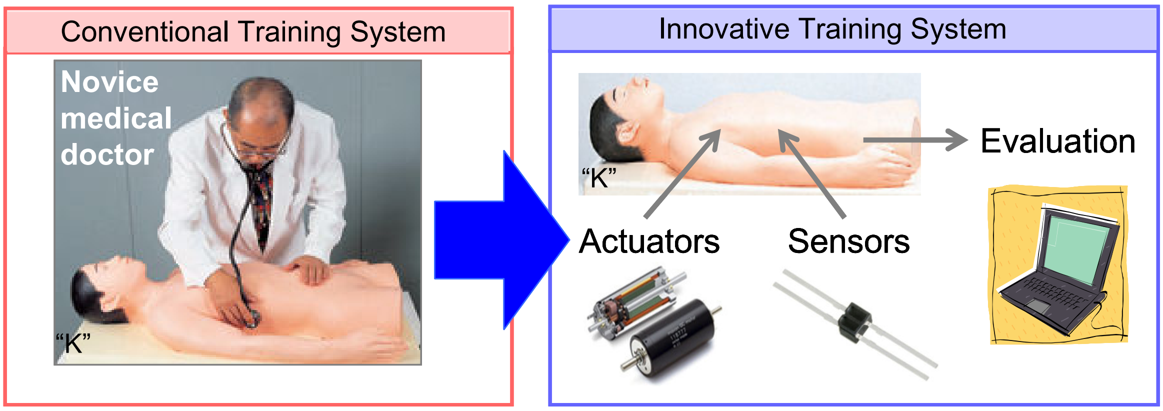


Figure 1.8 Conventional training system and innovative training system

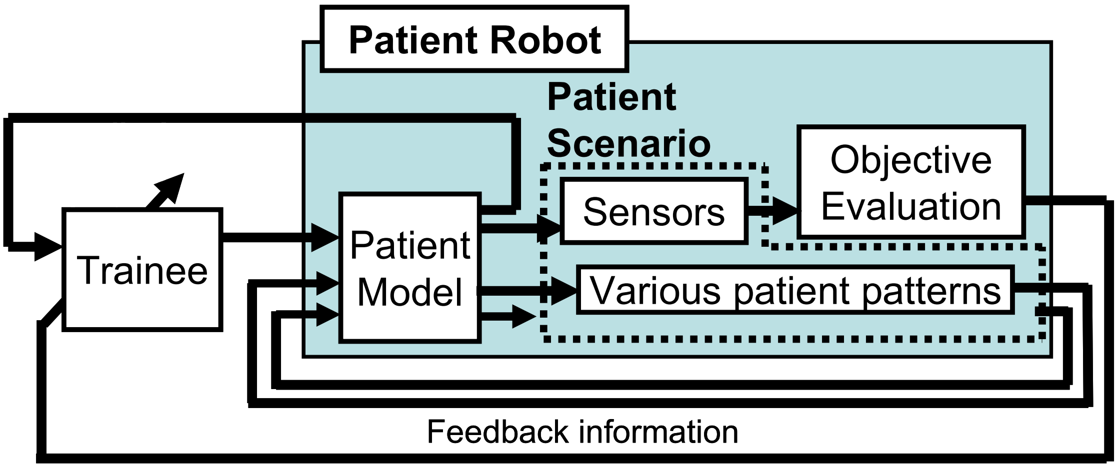


Figure 1.9 Concept of innovative training ystem

making it difficult to generate error counts. Checklists have been used to measure effectiveness (i.e., response correctness), but developing such a tool is time-consuming and can still involve some level of subjectivity [26]. Another measurement, efficiency (i.e., task completion time), has also been used to evaluate performance [27] [28], but this measurement may have limited applicability in studies emphasizing effectiveness. Researchers are now evaluating the utility of eye tracking [29] and situation awareness queries [30] as objective clinician performance metrics. In addition, they can not simulate real-world condition of the tasks: replicate human responses to clinical interventions. Since patient simulators do not "behave" exactly like real patients, clinicians may respond to simulated crises differently than they would if real patients were involved. Even that such kind of training systems reproduce some of the real-world conditions of the task, those issues may affect considerably the performance of trainees when they are requested to perform with real patients, especially in

Figure 1.10 Suturing training system

situations of emergency. Moreover, the conventional system can simulate few patient patterns. However, in the emergent situation, clinicians face to the various patients who have various cases, and individual differences. From these facts, the clinicians' performances may get used to the conventional training system, and they may not be able to cope with the real patient in the emergent situation.

1.2.2 Inovative Training System

Authors believe in the importance that an effective training system should be not only designed to reproduce the conditions of the tasks as well as to provide quantitative information of the trainees' progress [21][22]. Even that different kinds of innovative training systems have been proposed, most of them are designed to attach sensors on the medical instrument [23][31] (which in general provide information of specific parameters of the task performance). Furthermore, such innovative training systems are combined with virtual models or quite simple human body models [32][33]. For that purpose, the author has developed the innovative training system as a long-term project since April 2006 at Waseda

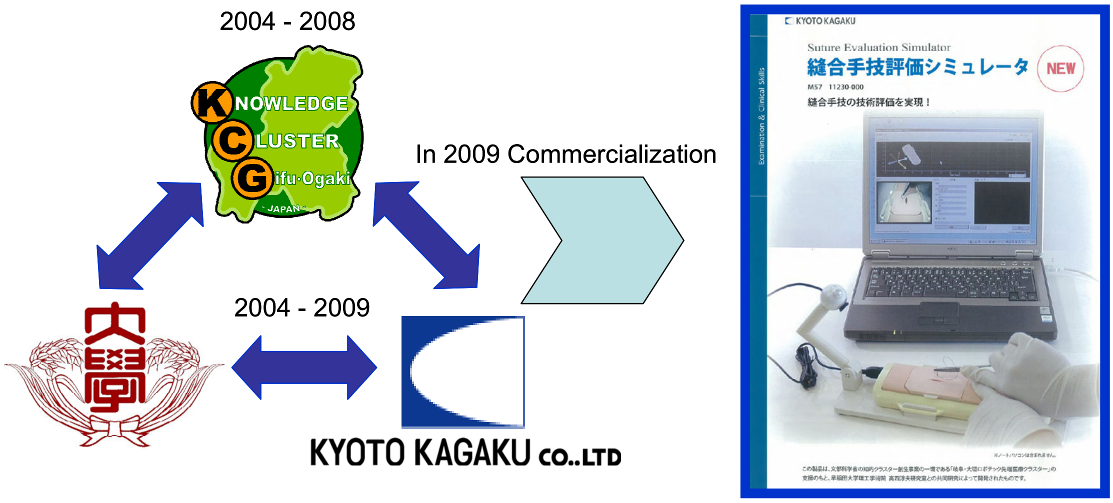


Figure 1.11 Commercialization for suturing training system

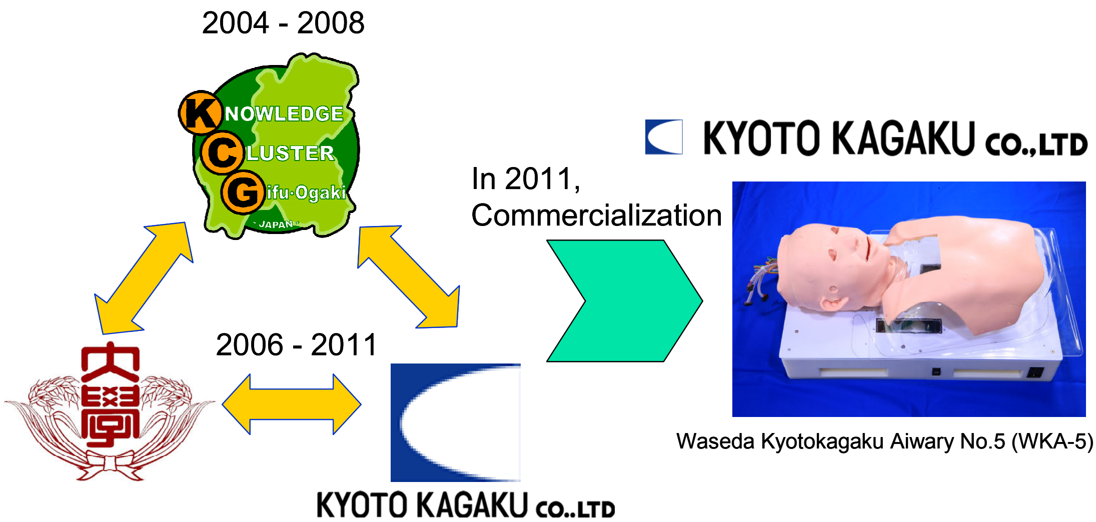


Figure 1.12 Commercialization for innovative training system for airway management

University. It may be used as an educational tool to train unskilled persons as well as an evaluation tool of medical procedures.

An inovative training system should be designed to emulate the human body (both anatomically and physiologically), have embed sensors into the simulator (not in the instrument) in order to obtain quantitative information of the trainee's performance of the task and provide objective assessment, and have embed actuators in order to reproduce the various patient patterns, and simulate real world condition of the tasks as shown in Fig. 1.8.

As shown in Fig. 1.9, the inovative training system should fulfill four requirements: 1) provide useful feedback to trainees and objective assessments of training progress, 2) reproduce the various patient patterns, 3) reproduce *Patient Scenario* for real-world conditions of the task and adjust degree of difficulty for trainee's effective training, and 4) simulate high-fidelity simulated human anatomy.

While the trainee is trained with a patient model which satisfies the high fidelity simulated human anatomy, the sensors embedded in the patient model obtain the quantitiave information of the trainees' performance. The unit of evaluation assesses the trainees' performance from the obtained quantitative information. The unit of evaluation provides feed back information to them. From this feed back information, they can understand their progress of their training. In addition, the unit of the various patient patterns can simulate a variety of the patients. In emergent situations or surgical operations, clinicians face to the various patients. For this reason, the unit of the various patient patterns makes the trainees improve thier copeability. The unit of the *Patient Scenario Generation* can replicate human responses to clinical interventions and "behave" exactly like real patients particularly in emergent situations and surgical operations. Such intervention and response make trainees' performance difficult. Therefore, it cannot only simulate real world conditions of the tasks of the patients, but also can adjust degree of difficulty for an effective medical training. Using this innovative training system, only without instructors or supervisors, the anthor expects that the trainee can improve their medical performance of the tasks.

1.2.3 Collaboration with Company and Commercialization

Since April 2004 at Waseda University, the author have proposed starting a long-term project which is supported by Knowledge Cluster Initiative, a project from the Ministry of Education, Culture, Sports, Science and Technology of Japan in order to develop a patient robot that may be used as an educational tool to train unskilled persons as well as an evaluation tool of experimental surgical instruments and medical procedures. For the purpose of this, as a first approach, Takanishi Lab. Waseda University has proposed a suturing training system which is called Waseda Kyotokagaku Suturing (WKS) series (Figure 1.10). This suturing training system can obtain quatitative information of the trainee's performance of the tasks, and provide objective assessment to the tranee [34][35][36][37][38][39][40]. In 2009, finally, Takanishi Lab commercialized them by collaborating with professional medical training company Kyotokagaku Co., Ltd (Figure 1.11). By the success of the commercialization, the company also requested us to develop an airway management training system. For the purpose of this, since 2006, Takanishi Lab has proposed the innovative Airway Management Training Systems (AMTS) which fulfill the four requirements of the innovative training system [41][42][43][44][45][46][47][48][49][50][51][52][53][54] (Figure 1.12).

1.3 Advantages of Innovative Training System

1.3.1 Effectiveness of Cost

Conventional systems have a small number of sensors, and provide little quantitative information to the trainee. They rely on instructors, normally professional doctors, for subjective assessment of trainee performance. For these reasons, it is preferable for trainees working with conventional systems to receive instructor guidance during the training sessions and during practice sessions with human volunteers. The expenses for the training and practice sessions are therefore proportional to the number of trainees. However, the proposed innovative training system can provide a great deal of quantitative information on trainee performance, which can be used to give objective assessment without the instructors. Trainees will still gain a better understating of their performance when instructors are present, but with the proposed system, the author expects only a few instructors will need to be present during the training and practice sessions. Consequently, the author expects that the expenses for the training and practice sessions will be smaller in relation to the number of trainees than with conventional systems, effectively reducing total expenses. Furthermore, the author also expects that our proposed training system will provide a more effective training experience than the conventional systems (Fig. 1.13-1.14).

1.3.2 Training Effectiveness

As stated in the previous section, the innovative training system provides quantitative feedback information to the trainee, and without instructors, the trainee can comprehend the training progress with the feed back information. Therefore, they can correct their performance of the task. From the results of the facts, the author believes that their performance will be improved using our proposed innovative training system. In other word, the innovative training system has the training effectiveness. In contrast, the convenional training system provides little feedback information to the trainee, and the author believes that their performance will not be improved compared to the innovative training system as shown in Fig. 1.15.

1.4 Purpose of This Research

There are many training methods based on the patient simulators. In this thesis, the author applies the concept of the innovative training system into the airway management, and focuses on the development of the innovative training system for the airway management, which satisfies its requirements of the innovative training system. Finally, through the

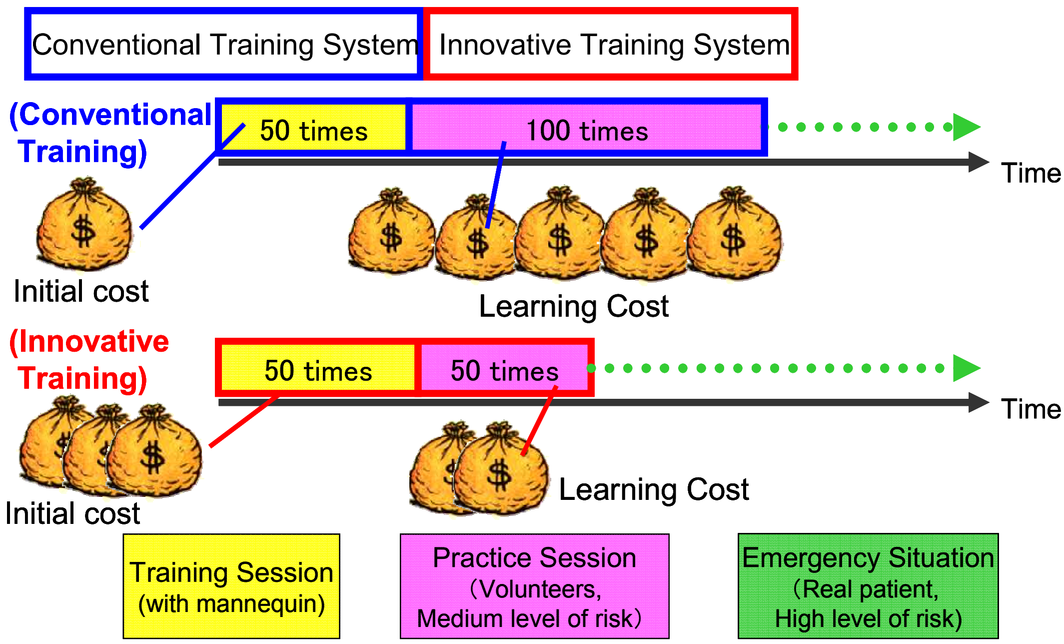


Figure 1.13 Comparison of initial cost between conventional training and innovative training

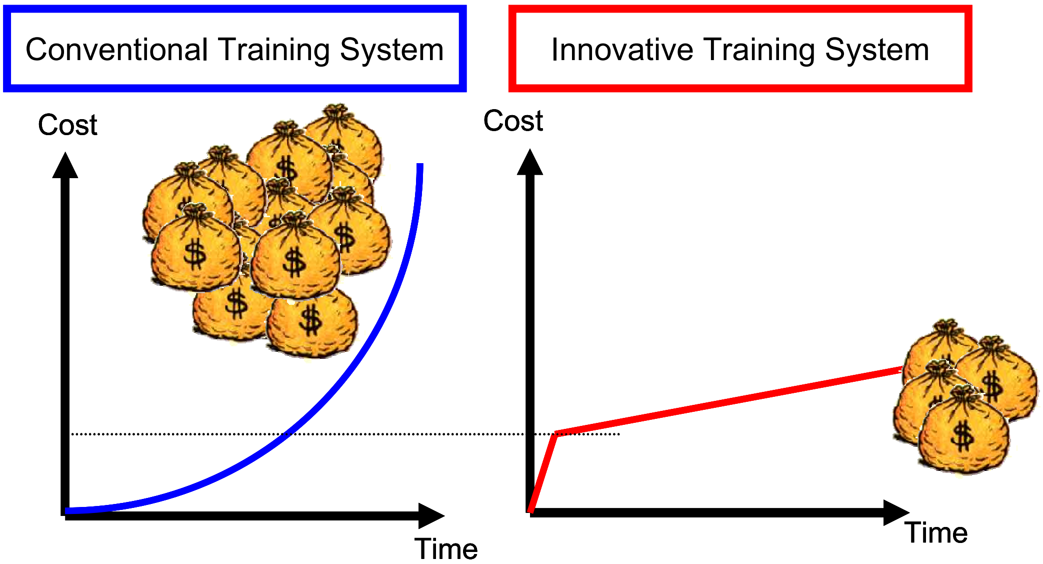


Figure 1.14 Comparison of total cost between conventional training system and innovative training system

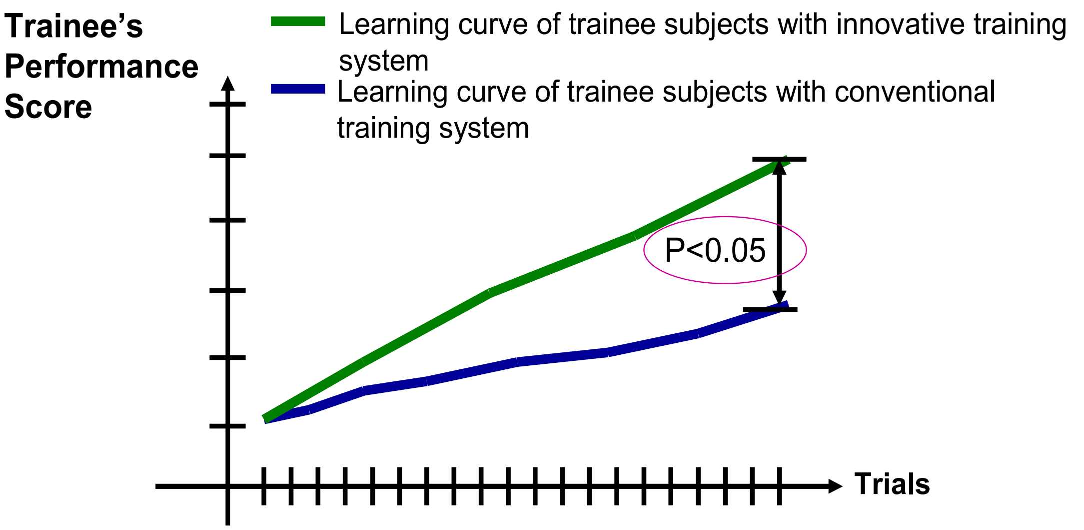


Figure 1.15 Verification of effectiveness of innovative training system

experiments with the innovative training system for the airway management, the author verifies the proposed innovative training system for the airway management, and establishes the design methodology for the development of the innovative training system for the airway management as purpose of this research.

In this section, the author presents airway management procedure, the various factors such as airway difficulties, and individual differences that the operators make the airway management difficult. In addition, the author presensts complications due to the unskilled performance, also presents the characteristics of the conventional training systems in detail, and present why the innovative training system should be required for the airway management training.

1.4.1 Airway Management

A) Tracheal Intubation

Tracheal intubation, usually simply referred to as intubation, is the placement of a flexible plastic tube into the trachea (windpipe) to maintain an open airway or to serve as a conduit through which to administer certain drugs (Figure 1.16). It is frequently performed in critically injured, ill or anesthetized patients to facilitate ventilation of the lungs, including mechanical ventilation, and to prevent the possibility of asphyxiation or airway obstruction (Figure 1.17-1.18). The most widely used route is orotracheal, in which an endotracheal tube is passed through the mouth and vocal apparatus into the trachea. In a nasotracheal procedure, an endotracheal tube is passed through the nose and vocal apparatus into the trachea (Figure 1.22-1.24). Other methods of intubation involve surgery and include the cricothyrotomy (used almost exclusively in emergency circumstances) and the tracheotomy, used primarily in situations where a prolonged need for airway support is anticipated [55][56][57].

Because it is an invasive and extremely uncomfortable medical procedure, intubation is usually performed after administration of general anesthesia and a neuromuscular-blocking drug. It can however be performed in the awake patient with local or topical anesthesia, or in an emergency without any anesthesia at all. Intubation is normally facilitated by using a conventional laryngoscope, flexible fiberoptic bronchoscope or video laryngoscope or airway scope to identify the glottis, though other devices and techniques are available (Figure 1.19-1.21). After the trachea has been intubated, a balloon cuff is typically inflated near the far end of the tube to help secure it in place, to prevent leakage of respiratory gases, and to protect the tracheobronchial tree from receiving undesirable material such as stomach acid. The tube is then secured to the face or neck and connected to a T-piece, anesthesia breathing circuit, bag valve mask device, or a mechanical ventilator. Once there is no longer a need for ventilatory assistance and/or protection of the airway, the tracheal tube is removed; this is referred to as extubation of the trachea (or decannulation, in the case of a surgical airway such as a cricothyrotomy or a tracheotomy) [58].

B) Complications

Tracheal intubation can be associated with minor complications such as broken teeth or lacerations of the tissues of the upper airway, or potentially fatal complications such as pulmonary aspiration of stomach contents or unrecognized intubation of the esophagus (Figure 1.25). Because of this, the potential for difficulty or complications due to the presence of unusual airway anatomy or other uncontrolled variables is carefully evaluated before undertaking tracheal intubation. Alternative strategies for securing the airway must always be readily available. The incidence of serious complications is unacceptably high when undertaken by practitioners lacking adequate training and experience [59][60][61][62][63][64].

C) Influence of Airway Difficulties and Individual Differences

Tracheal intubation is not a simple procedure and the consequences of failure are grave. Therefore, the patient is carefully evaluated for potential difficulty or complications beforehand. This involves taking the medical history of the patient and performing a physical examination, the results of which can be scored against one of several classification systems. The proposed surgical procedure (e.g., surgery involving the head and neck, or bariatric surgery) may lead one to anticipate difficulties with intubation [65][66]. Many individual differences have unusual airway anatomy, such as those who have limited movement of their neck or jaw, or those who have tumors, deep swelling due to injury or to allergy, developmental abnormalities of the jaw, or excess fatty tissue of the face and neck (Figure 1.26-1.29). Using conventional laryngoscopic techniques, intubation of the trachea can be difficult or even impossible in such patients. This is why all persons performing tracheal intubation must be familiar with alternative techniques of securing the airway. Use of the flexible fiberoptic bronchoscope and similar devices has become among the preferred techniques in the management of such cases. However, these devices require a different skill set than that employed for conventional laryngoscopy and are expensive to purchase, maintain and repair.

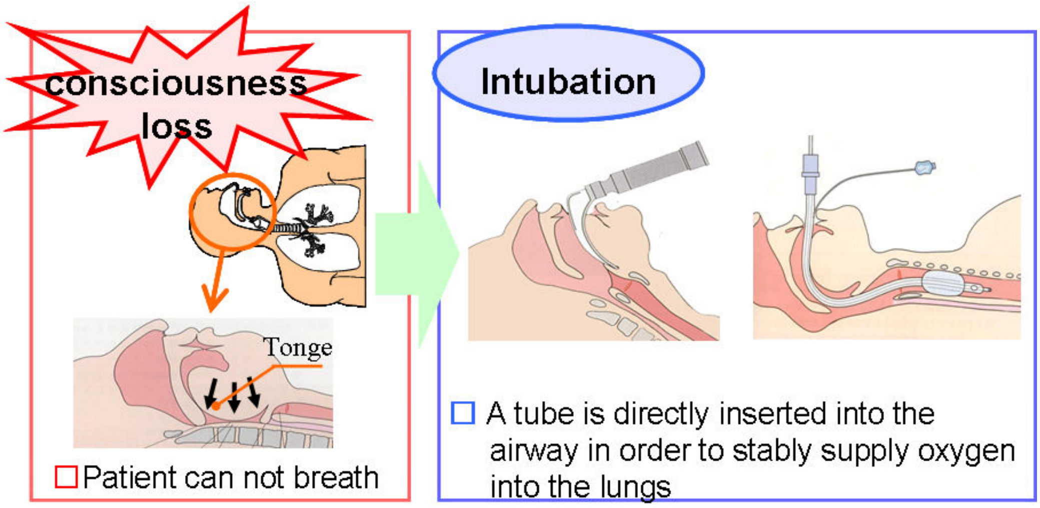


Figure 1.16 Neccisity of airway management

Figure 1.17 Performance of airway management

When taking the patient's medical history, the subject is questioned about any significant signs or symptoms, such as difficulty in speaking or difficulty in breathing. These may suggest obstructing lesions in various locations within the upper airway, larynx, or tracheobronchial tree. A history of previous surgery (e.g., previous cervical fusion), injury, radiation therapy, or tumors involving the head, neck and upper chest can also provide clues to a potentially difficult intubation. Previous experiences with tracheal intubation, especially difficult intubation, intubation for prolonged duration (e.g., intensive care unit) or prior tracheotomy are also noted.

A detailed physical examination of the airway is important, particularly:

Figure 1.18 Provision of oxygen by endotracheal tube

Figure 1.19 Devices for airway management

Figure 1.20 Airway scope (Pentax)

Figure 1.21 flexible fiberoptic bronchoscope

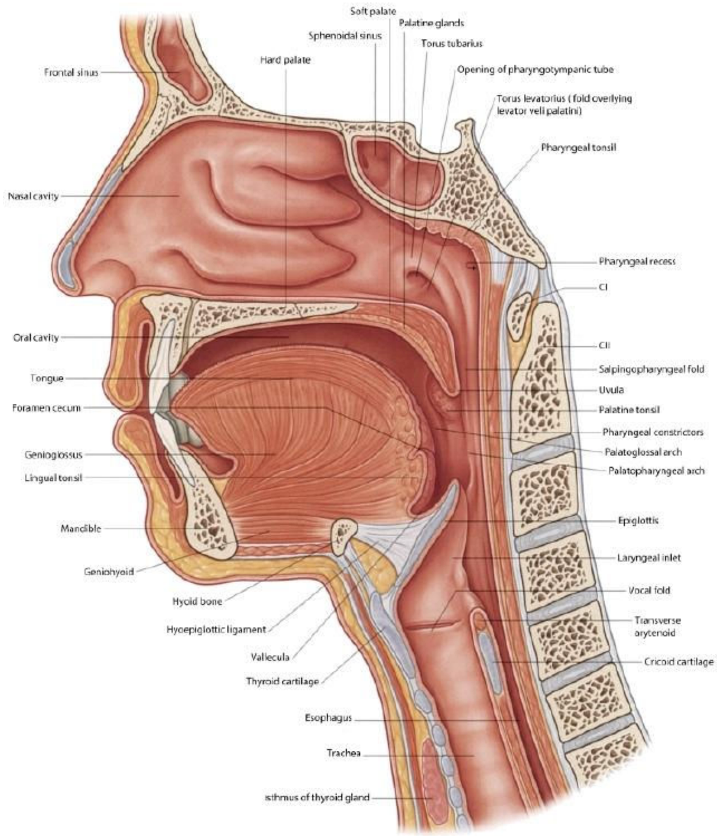


Figure 1.22 Human anatomy of head and neck

- the range of motion of the cervical spine: the subject should be able to tilt the head back and then forward so that the chin touches the chest.
- the range of motion of the jaw (the temporomandibular joint): three of the subject's fingers should be able to fit between the upper and lower incisors.

- the size and shape of the upper jaw and lower jaw, looking especially for problems such as maxillary hypoplasia (an underdeveloped upper jaw), micrognathia (an abnormally small jaw), or retrognathia (misalignment of the upper and lower jaw).
- the thyromental distance: three of the subject's fingers should be able to fit between the Adam's apple and the chin.
- the size and shape of the tongue and palate relative to the size of the mouth.
- the teeth, especially noting the presence of prominent maxillary incisors, any loose or damaged teeth, or crowns.

Many classification systems have been developed in an effort to predict difficulty of tracheal intubation, including the Cormack-Lehane grading system (Figure 1.29), the Intubation Difficulty Scale (IDS), and the Mallampati score as shown in Fig. 1.28. The Mallampati score is drawn from the observation that the size of the base of the tongue influences the difficulty of intubation. It is determined by looking at the anatomy of the mouth, and in particular the visibility of the base of palatine uvula, faucial pillars and the soft palate. Although such medical scoring systems may aid in the evaluation of patients, no single score or combination of scores can be trusted to specifically detect all and only those patients who are difficult to intubate. Furthermore, one study of experienced anesthesiologists, on the widely used Cormack–Lehane classification system, found they did not score the same patients consistently over time, and that only 25% could correctly define all four grades of the widely used Cormack–Lehane classification. emergency circumstances (e.g., severe head trauma or suspected cervical spine injury), it may be impossible to fully utilize these the physical examination and the various classification systems to predict the difficulty of tracheal intubation. In such cases, alternative techniques of securing the airway must be readily available.

1.4.2 Conventional Airway Management Simulators

There are currently many kinds of the airway management training simulators, developed by a range of companies. Some HCMS (High Cost Medical Simulators) can simulate high fidelity simulated anatomy, have functions which enable trainees to train not only airway management, but also general anesthesiology and various other medical tasks. In addition, the HCMS can simulate not only the airway difficults, but also simulate various

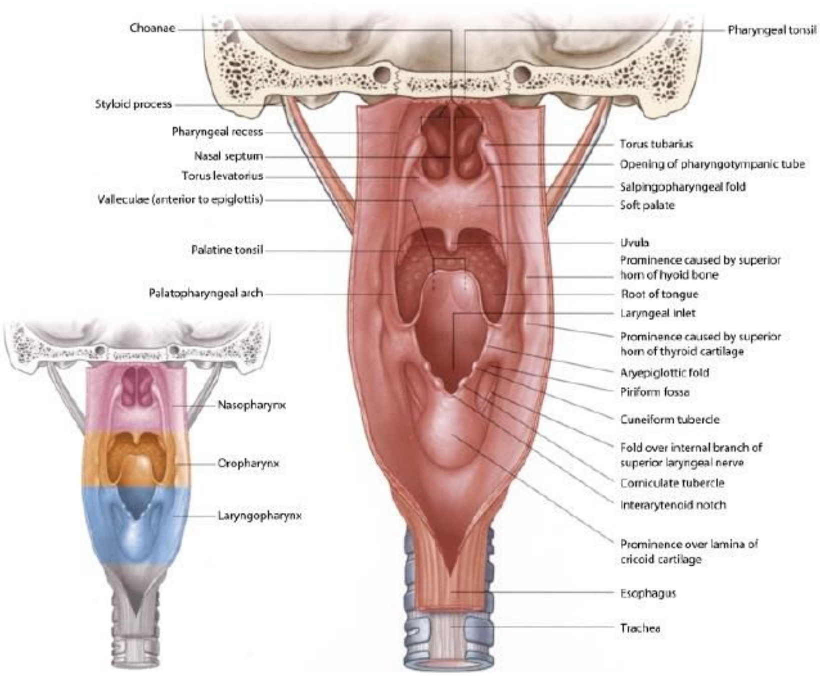


Figure 1.23 Human anatomy of upper airway

states of the patient such as blood pressure, blood oxygen level, and responses of medicines (Figure 1.6-1.7). LCMS (Low Cost Medical Simulators) can also simulate high fidelity simulated anatomy, but only allow the trainees to train airway management (Figure 1.30-1.31), and reproduce few airway difficulties. LCMS has no sensor, so it does not provide feedback information to the trainee. HCMS has few sensors, so it provides little feedback information to the trainees. Therefore, using these conventional training simulators, the trainee should be trained with instructors who provide feedback information to the trainee (Figure 1.32-1.33).

The stiffness of mandible, tongue, and neck of the both of two simulators are harder than one of the patients, and the stiffness of the two simulators are not similar with the one of human, so the motions of the tongue, mandible, and neck are not similar woth the ones of the human by the medical device while peforming the airway management. Therefore, the trainees who were trained with the conventional training simulators get used to apply the strong force on these simulators. For this reason, they tried to apply strong force on the tongue, mandible, and neck of the patients of the patients while performing the airway management, and finally, their performances traumatize the patients. As results of these facts, neither type of conventional system can fulfill the requirements of the effective, innovative training system (Figure 1.32 and 1.33), and the trainee cannot be trained effectively and efficiently. Although

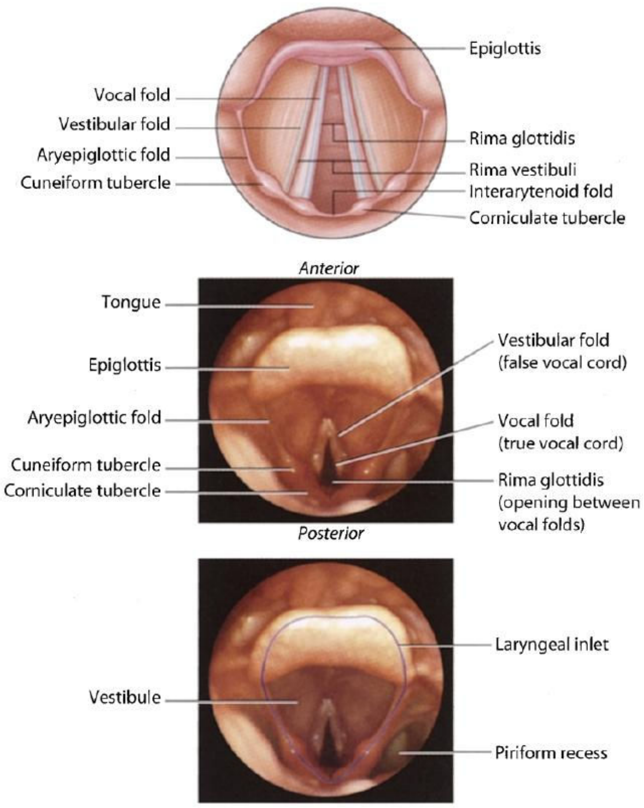


Figure 1.24 Human anatomy of larynx

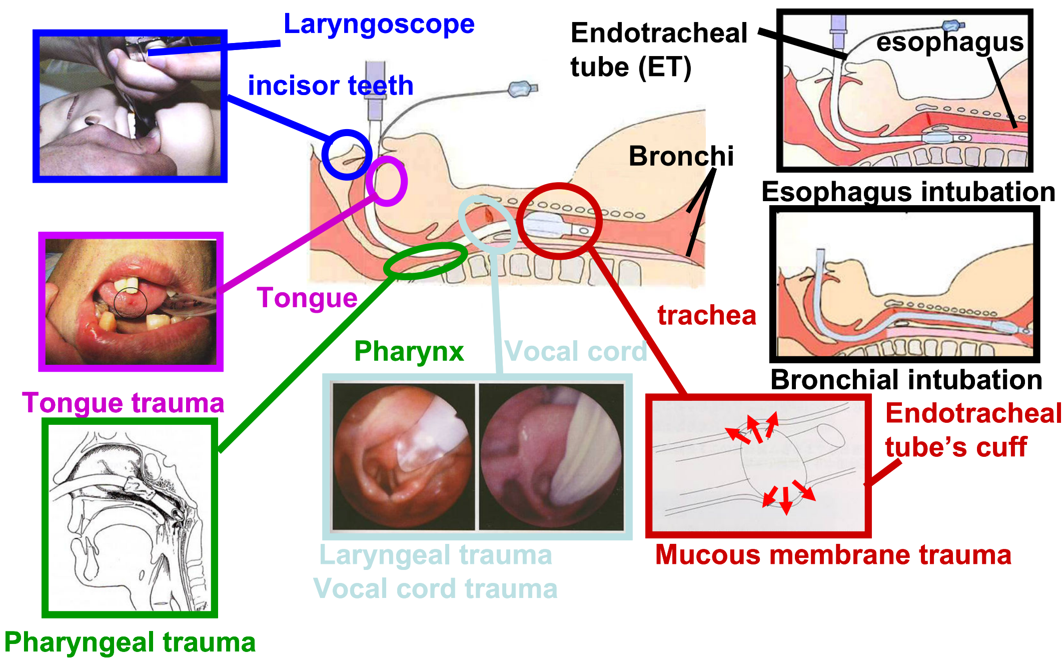


Figure 1.25 Complications due to unskilled performance

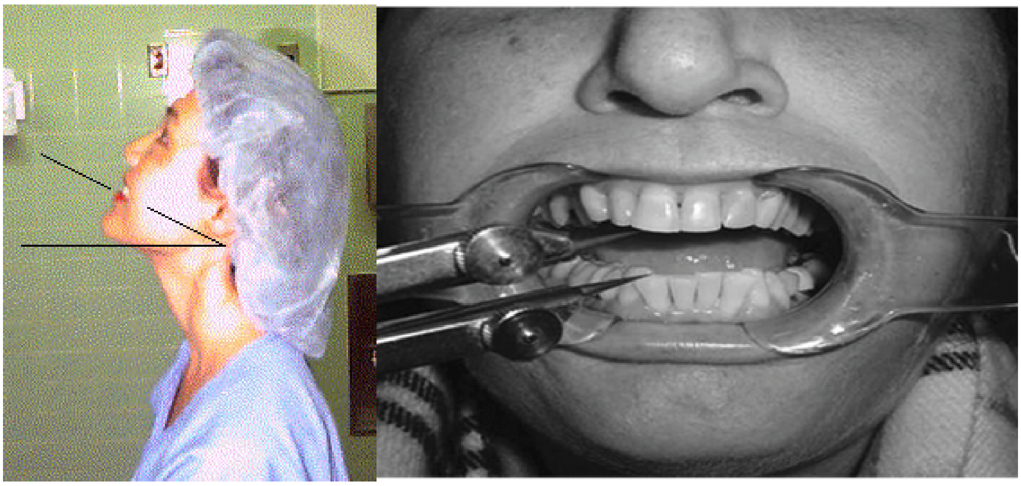


Figure 1.26 Airway difficulty: restricted cervical range and restricted opening mouth

Figure 1.27 Airway difficulty: Tongue edema

the HCMS has the various functions compared to the LCMS for the airway management, either type of the conventional system are all but same.

Therefore, the author proposes an innovative training system (ITS) for the airway management which not only satisfies its requirements, but also can be provided at a relatively low cost—more than existing low cost simulators, but less than existing high cost simulators (Figure 1.31).

1.4.3 Propose Innovative Training System for Airway Management, and Technical Originality of Our System

Our proposed innovative training system for the airway management must fulfill four requirments: it must 1) provide useful feedback to trainees and objective assessments of training progress, 2) reproduce the various patient patterns, 3) reproduce *Patient Scenario* for real-world conditions of the task and adjust degree of difficulty for trainee's effective training, and 4) simulate high-fidelity simulated human anatomy.

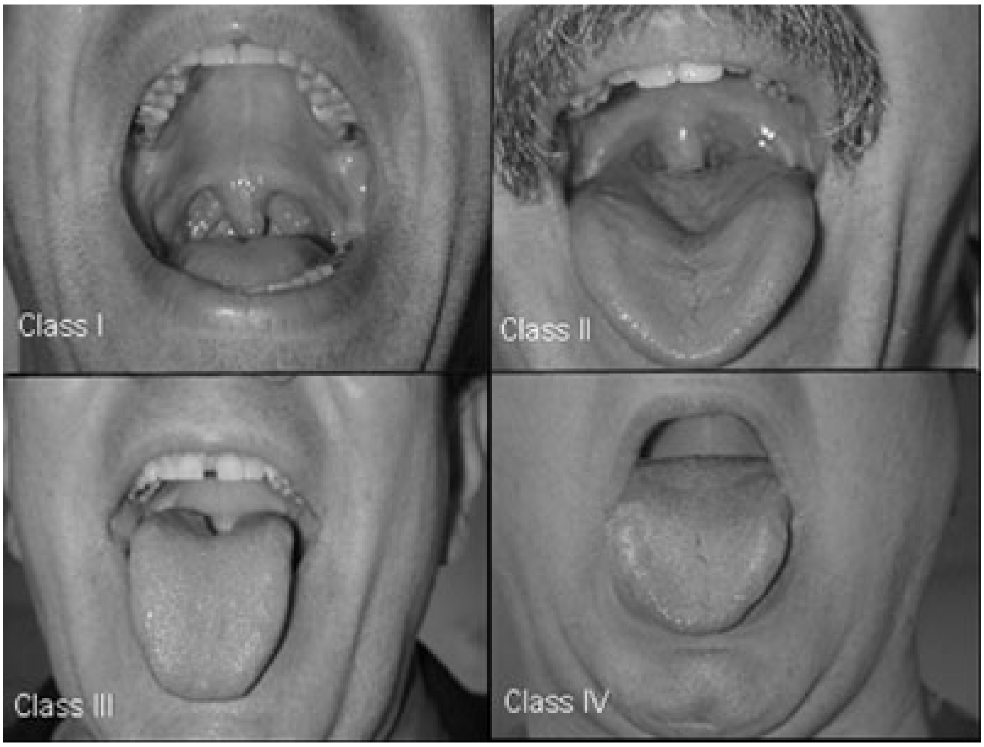


Figure 1.28 Mallampati score

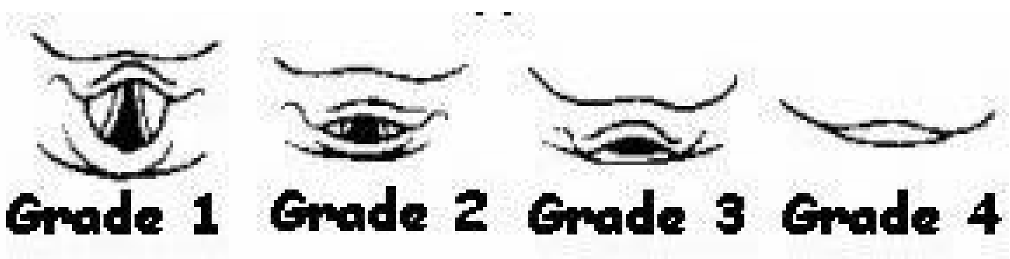


Figure 1.29 Cormack–Lehane classification system

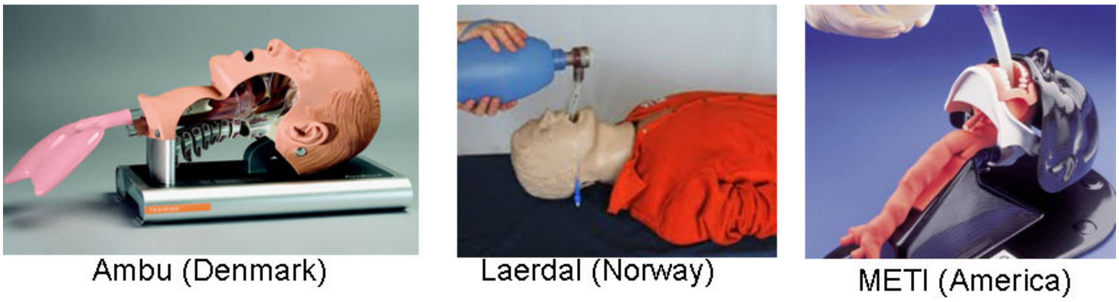


Figure 1.30 Low cost medical simulators for airway management training

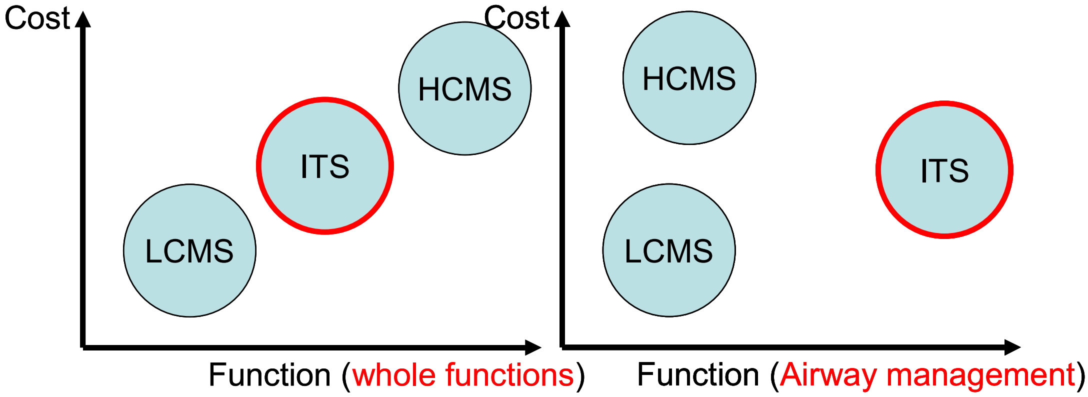


Figure 1.31 Conventional training system (LCMS and HCMS) vs innovative training system

For the purpose of requirement 1), the proposed innovative training system has many sensors to provide quantitiative information of the trainee's performance, and provide objective assessments of the training progress during the airway management. This can provide quantitiative feedback information to the trainee, the feedback information can correct their wrong performance of the task. For the purpose of requirement 2), it has many sensors and actuators to simulate the various patient patterns such as airway difficulties, individual difference of the human anatomy, and stiffness of the human's muscles. Particularly, it can reproduce not only relaxed and soft muscles while the the patients are unconscious under the general anesthesia, but also contracted and harden muscles on the patient's neck, tongue, and head while the patients are concioueness during self-regulation of respiratory during the airway management. Moreover, it can also reproduce a variety of stiffnesses of the human's muscles because according to the humans, they have different stiffnesses. From the requirement, the trainee can be trained with the various patients

For the purpose of requirement 3), it has a *Patient Scenario* for real-world conditions of the task and adjusts degree of difficulty for trainee's effective training. The *Patient Scenario* can replicate human responses to clinical interventions and "behave" exactly like real patients particularly in emergent situations and surgical operations. Such intervention and response make trainees' performance difficult. Therefore, it cannot only simulate real world conditions of the tasks of the patients, but also can adjust degree of difficulty for an effective medical training. For the purpose of requirement 4), it has high-fidelity simulated human anatomy for the real world condition of the task.of the real patients. Using this innovative training system, only with a few instructors, the anthor expects that the trainee can improve their medical performance of the tasks.

Therefore, the author expects that our proposed innovative training system have many advantages in the field of the airway management, and is lower cost (more expensive than the LCMS, and cheaper than HCMS). Finally, in the market, our system will have a strong priority, and contribute to competition in the field of the training system.

1.5 Construction of This Thesis

As the author stated in the chapter one, an innovative training system must fulfill four specific conditions: it must 1) provide useful feedback to trainees and objective assessments of training progress, 2) reproduce the various patient patterns, 3) reproduce *Patient Scenario* for real-world conditions of the task and adjust degree of difficulty for trainee's effective training, and 4) simulate high-fidelity simulated human anatomy as shown in Fig. 1.9. For the innovative training system, the author used actuators and sensor systems as the main elements. In order to establish design methodology for the innovative training system, the author has proposed the training system which can fulfill one of the requirements of the innovative training system, and from the experiements, and established each of the requirements of the innovative training system. Finally, the author intergrates each of the requirements of the innovative training system into the one system, and from the experiments established the design methodology of the innovative training system for the airway management.

For these plans, since 2006, the author has developed four WKA (Waseda KyotoKagaku Airway) series. In this section, the author presents the development details of

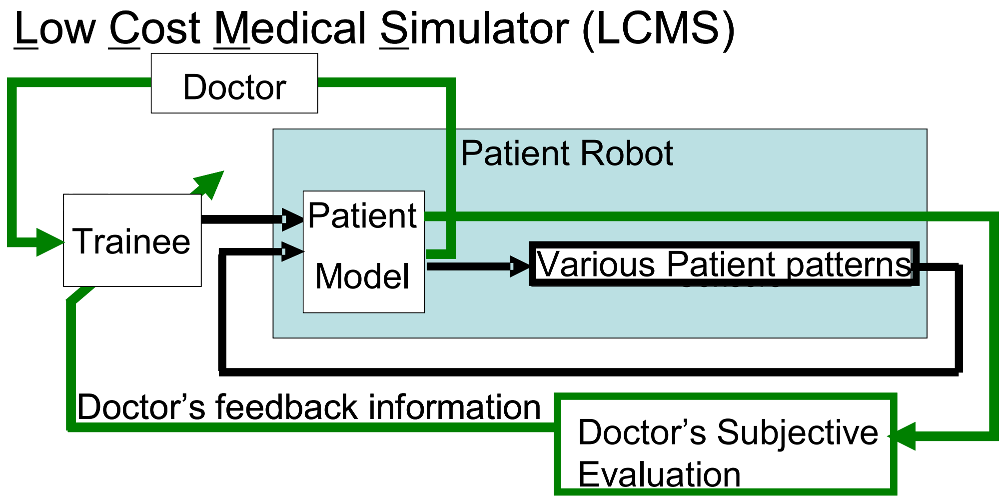


Figure 1.32 Low cost medical simulators for airway management training

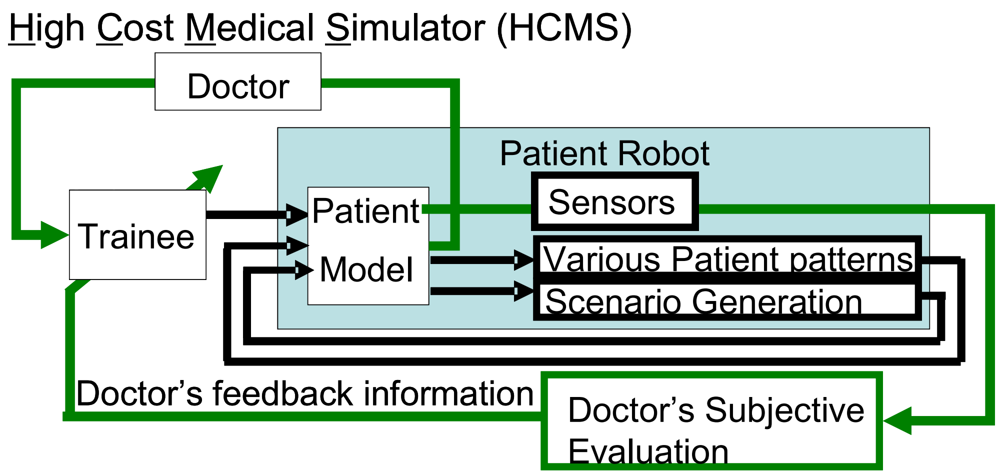


Figure 1.33 High cost medical simulators for airway management training

the innovative airway management training system, introduce purpose of each of WKA series, and presents how to achieve each of the requirments for the innovative training system. In addition, as shown in Fig. 1.37, the author would like to explan how close each of the chapters has connections and relationship.

1.5.1 Chapter 1

In the chapter one, the author introduces general simulation systems and the simulation systems used in training and education, focusing on simulations for medical

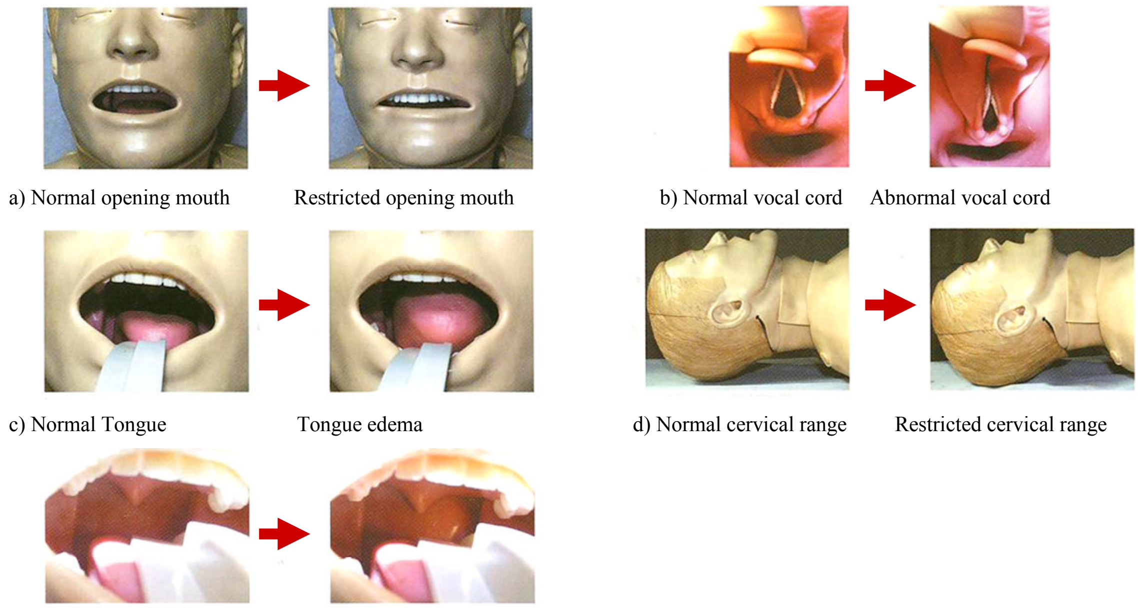


Figure 1.34 Airway difficuties simulated by HCMS

training. The author also proposes the general concept of the innovative training system in comparison with conventional training systems, and states the purpose of this research.

1.5.2 Chapter 2

In the chapter two, the author establishes a way to provide quantitative information of the trainee's performance of the tasks to trainee while performing airway management, and provide objective assessment using sensor systems and evaluation unit. For the purpose of these facts, the author proposed two methods:

1) Proposed sensor systems and WKA-1R in order to obtain quatitative information of the trainee's performance of the task while performing the airway management.
2) Propose an evaluation function to provide objective assessment of the trainee's performance while performing the airway management.

For the proposed first method, the author proposed WKA-1R (Waseda Kyotokagaku Airway No.1 Refined) which embeds four kinds of the sensor systems such as FDSS, improved FDSS, PDSS, and DDSS. They can detect the difference of the level of the trainee's performance while performing the airway management. For the proposed second method, the

	ディフィカルトエアウエイシミュレーター AirMan	気道管理トレーナ	SimMan	気管挿管訓練モデル 喜々一発	SAVEMAN	サカモト気管挿管トレーナー	ECS	WKA
発売元	レールダルメディカルジャパン（株）	レールダルメディカルジャパン（株）	レールダルメディカルジャパン（株）	（株）高研	（株）高研	（株）坂本モデル	（株）IMI	(株)京都科学･早稲田
用手気道確保	○	○	○	○	○	○	○	○
各種器具を用いた経口・経鼻挿管	○	○	○	○	○	○	○	○
片肺挿管	○	○	○	○	○	○	○	○
バッグ・バルブ・マスク換気	○	○	○	△構造上リーク発生	△構造上リーク発生	○	○	○
エアウエイの使用	○	○	○	○	○	○	○	○
呼吸音の聴診	○	○	○	○	○	○	○	○
喉頭鏡の使用	○	○	○	○	○	○	○	○
喉頭鏡の不適正な使用時の警告	○力が加わると歯が折れる	○信号音が発生	○力が加わると歯が折れる	○信号音が発生	○信号音が発生	○力が加わると歯が折れる	○力が加わると歯が折れる	○
気道損傷の再現	×	×	×	○	×	○	×	○
上気道閉塞の再現	×	×	×	×	×	×	×	○
挿管困難症例の再現								○
開口障害	○	×	○	×	×	×	○	○
舌浮腫	○	×	○	×	×	×	○	○
咽頭閉塞	○	×	○	×	×	×	○	○
喉頭痙攣	○	○	○	×	×	×	○	○
頚部可動域の制限	○	×	○	×	×	×	×	○
挿管不可－換気可、挿管不可－換気不可状態の再現	○	×	○	×	×	×	○	○
気管支鏡トレーニング	○	○（オプション品装着にて可能）	○	×	×	×	×	○
気道閉塞シミュレート	○	×	○	×	×	×	○	○
胃膨満シミュレート	○	○	○	○	○	○	○	○
胃内容物の逆流シミュレート	×	○	×	○	×	×	○	○
筋肉の硬さの再現	×	×	×	×	×	×	×	○
気管挿管患者シナリオ再現	×	×	×	×	×	×	×	○
気管挿管手技評価	×	×	×	×	×	×	×	○
手技の定量的な情報の取得	×	×	×	×	×	×	×	○
心臓マッサージ	○	×	○	×	○	×	○	×
頚動脈の触診	○心拍数設定に連動	×	○心拍数設定に連動	×	○心拍数設定に連動	×	○心拍数設定に連動	×
輪状甲状靱帯穿刺・切開	○	×	○	×	×	×	○	×
胸腔穿刺	○	×	○	×	×	×	○	×
胸腔ドレーン挿入	○（オプション）	×	○	×	×	×	○	×
心膜穿刺	×	×	×	×	×	×	○	×
下肢を装着しての搬送トレーニング	○（オプション）	×	○	×	○	×	○	×
外傷処置トレーニング	○（オプション）	×	○	×	○	×	○	×
止血トレーニング	○（オプション）	×	○	×	○	×	○	×
創傷ケアトレーニング	○（オプション）	×	○	×	○	×	○	×
口腔・涙嚢分泌	×	×	×	×	×	×	○	×
IVトレーニング	○	×	○	×	○	×	○	×
導尿トレーニング	○（オプション）	×	○	×	○（オプション）	×	○	×
Spo2表示	○プローブ付属	×	○プローブ付属	×	×	×	○プローブ付属	×
心拍数表示	○	×	○	×	○	×	○	×
リモコンを用いての操作	有線及びワイヤレス	−	有線及びワイヤレス	−	ワイヤレス	−	有線及びワイヤレス	×

Figure 1.35 Characterisitcs of LCMS, HCMS, and ITS for management training

author proposed an evaluation function to provide objective assessment of the trainee's performance while performing the airway management. For the evaluation function, a set of threshold values for the normalization were considered referring to the average data of unskilled subject group, anesthetist group, and medical literature. In order to determine weigh coefficients of evaluation function, the author applied discriminant analysis.

In order to verify the effectiveness of the proposed methods, two experiments have been carried out with doctor subjects and unskilled student subjects. From the result of the first experiment, the WKA-1R which embeds the FDSS, the improved FDSS, the DDSS, and PDSS can detect the difference of the level of the trainee's performance while performing the airway management. Therefore, the author verified the effectiveness of the proposed sensor system and WKA-1R. From the result of the second experiment, the author could find significant differences between the score of anesthetist group and unskilled subject group. From the result of the fact, the author verified the effectiveness of the proposed evaualtion function.

Although the FDSS and the improved FDSS can measure quantitative information, they have several problems. First, for the measurement of the applied force, the sensor should be required for the deformation because without changing the distance between the photo interrupter and the white reflective plastic. Second, the FDSS and the improved FDSS can measure only compressive force. For the other applications, the sensor system should be required for the generality. It should not only be used in our system, but also in other applications. Therefore, the author found the necessity to develop and redesign a new sensor system for the practical applications and for the generality. As a result of these facts, they should be considered in in the chapter 3.

1.5.3 Chapter 3

In the chapter three, the author establishes a way to reproduce the various patient patterns by reproducing various airway difficulty cases and individual airway difficulties and by simulating stiffness of the human muscle using actuators and sensors. For the accomplishment of these, the author poroposes three methods:

1) Propose sensor systems in order to measure an amount of force information which can measure compression, and tension for the generiality. In addition, consider generality and practical application for the proposed sensor system.
2) Propose mechanical mechanism of the training system WKA-2 which can reproduce various patient patterns such as airway difficultes, and individual differences
3) Propose control system for the determination of the position and for the simulation of the various stiffnesses of the patient's muscles.

For the proposed first method, the author designed the principle of the sensor system TCDSS. The TCDSS can measure an amount of force information which can measure compression, and tension for the generiality. For the proposed second method, by employing wire driving mechanismin, the WKA-2 can reproduce various patient patterns such as airway difficultes, individual differences. For the proposed third method, by applying *Virtual Compliance Control* into the wire driving mechanism, the WKA-2 can simulate the various range of the stiffness of the human's muscle.

In order to verify the effectiveness of the proposed methods, three experiments have been carried out. From the result of the first experiment, the author verified the effectiveness of the proposed sensor system TCDSS. From the result of the second experiment, the WKA-2 could reproduce various patient patterns such as airway difficultes, individual differences, and

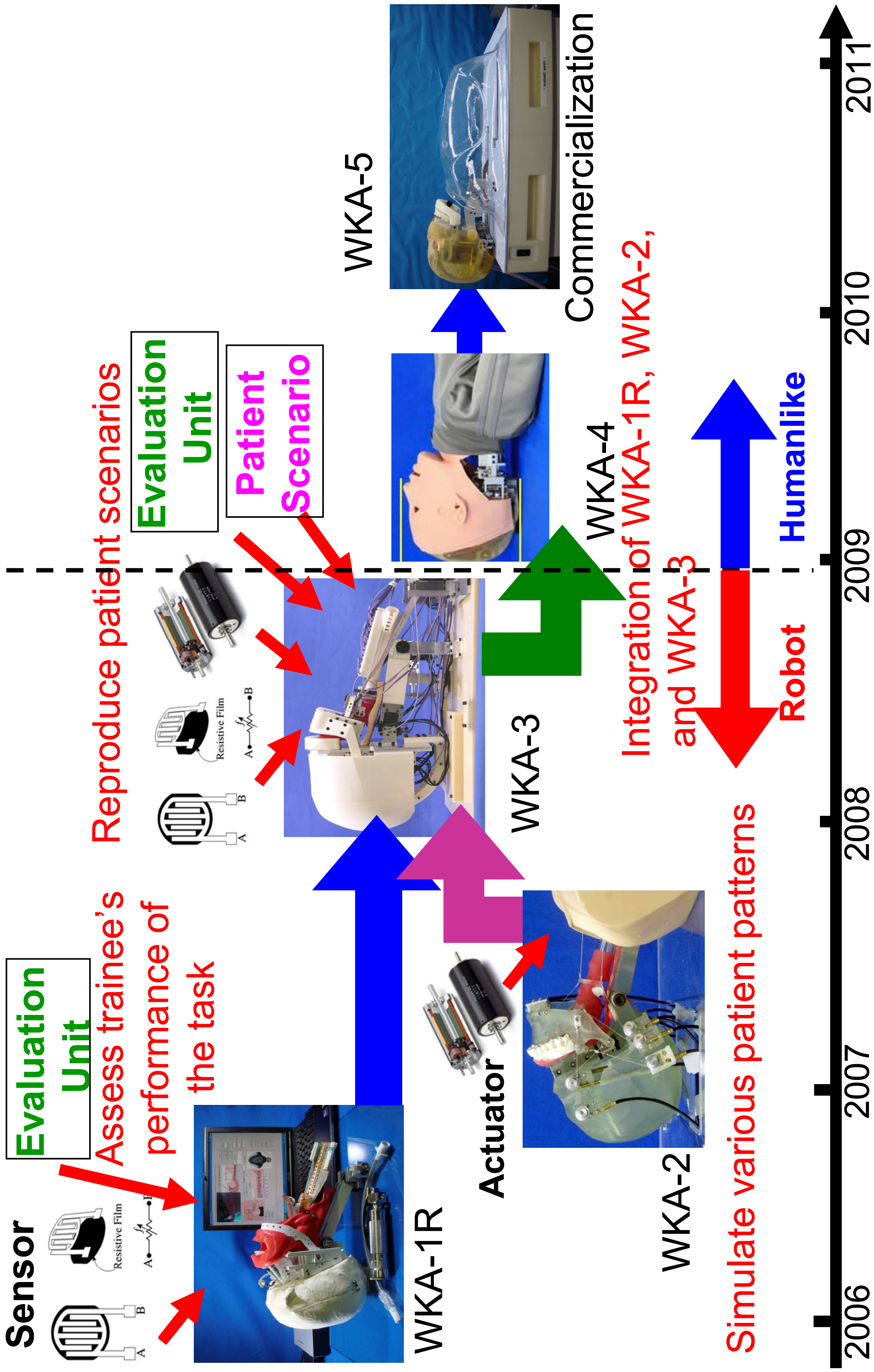


Figure 1.36 History of Waseda KyotoKagaku Airway (WKA) Series

the author verified the effectiveness of the proposed mechanism. From the result of the third experiment, the author found the position errors due to the wire driving mechanism, and could simulate the various range of the stiffness of the human's muscle by applying *Virtual Compliance Control*. Finally, the author verified the effectiveness of the proposed control system.

Although the WKA-2 can reproduce the various patient patterns such as airway difficulties, individual differences in human anatomy, and simulation of the stiffness of the human's muscles. However, the complexity of the wire driving mechanism can not apply the *Virtual Compliance Control* into the training system WKA-2, and causes each of the wires to be slacked. The author should consider these problems into the next chapter how to improve them. In addition, the WKA-2 focuses on the time invariant characteristics of the patients, and these cannot satisfy the reproduction of the real-world condition of the task completely. In emergent situation or surgical operation, the patients are not stationary, and dynamically change their characteristics according to medical treatments or trainees' performance (dynamic or time variant characteristics of the patients). As a result of these facts, not only the static characteristics of the patients should be considered in reproducing real-world condition of the task in the chapter 4.

1.5.4 Chapter 4

In this chapter four, the author establishes the *Patient Scenario Algorithm* for the one of the requirements of the innovative training system for the airway management using the WKA-3 which is integrated with the actuators and sensors, and for this reason, the author proposed three methods as follows.

1) Consider mechanism which enables sensors and actuators to be integrated for the data acquisition of the trainee's performance, and for the reproduction of the various patient patterns which satsfy human anatomy
2) Propose control system and for the simulation of the stiffness of the patient's muscles and *Propose Patient Scenario Generation*, and propose how to implement it into the training system
3) Compare the training effeciveness between a normal medical training and a medical training based on scenario which makes the airway management difficult.

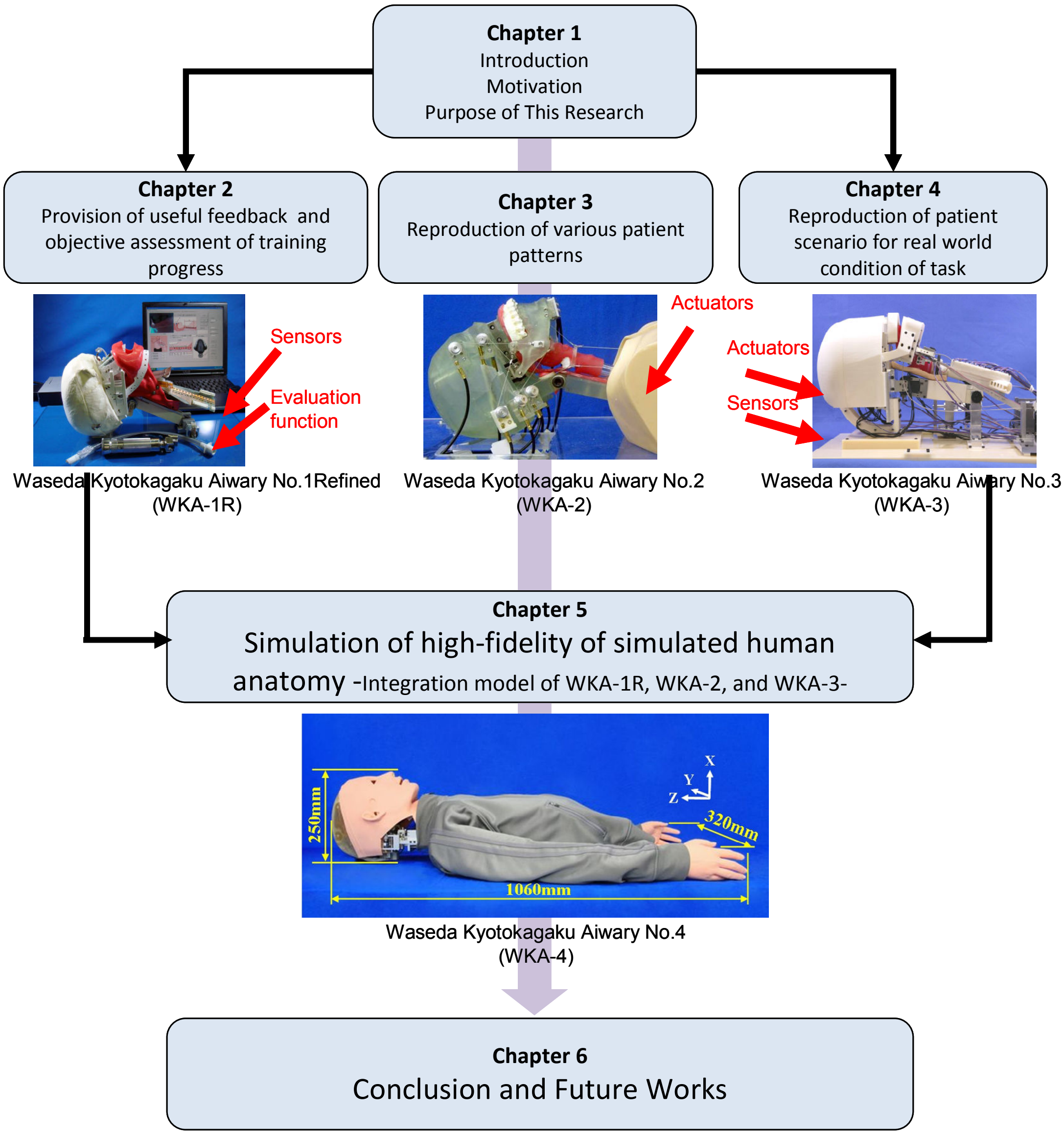


Figure 1.37 Draft flow line of this thesis

For the proposed first method, the author proposed link drive mechanism and wire driving mechanism which can reproduce various patient patters such as airway difficulties, and individual differences, and the four kinds of sensor systems are embedded into the parts of the redesigned organs of the patient model. For the proposed second method, the author proposes control sysem in order to simulate various ranges of the human's muscles same as the author applied the *Virtual Compliance Control* in the chapter 3, and to reproduce the *Patient Scenario Generation* for real world condition of the task. For the proposed third method, the author compares the training effeciveness between the normal medical training system and the scenario medical training whether the training based on the scenario can make airway menangement difficult or not.

In order to verify the effectiveness of the proposed methods, three experiments have been carried out. From the result of the first experiment, the proposed mechanism can improve not only the robust but also perform the airway management. In addition, the proposed mechanism could satisfy the reproduction of the various patient patterns such as airway difficulties, and individual difference in human anatomy. Through the doctor's opinions, the proposed mechanism was verified, and the author found the facts how to improve the mechanism. From the result of the second experiment, the author verified the effectivenss of the proposed control system for the simulation of the stiffness of the human's muscles. Moreover, the author verified the *Patient Scenario Algorithm* reproduced by actuators and sensors. The doctor subjects gave variable opinions on the two reproductions of the *Patient Scenario*, and from the doctor subject opinions, our proposed *Patient Scenario Generation* could be verified. From the result of the third experiment, as the training trials rises, the normal training group found training effectiveness through the learning curve. In constrast, the scenario training group could not find the training effectiveness through the learning curve. From the results of the facts, the author found the fact that during the patient scenario (the emergency or the surgical operation) can adjust level of difficulty of the airway management. Therefore, the author found the effectiveness of the proposed *Patient Scenario Algorithm*.

Although the WKA-3 fulfills three requriments of the innovative training system, it could not simulate high fidelity of the human anatomy because the upper airway, larynx and pharynx, esophagus, oral cavity, nasal cavity, and lung cannot be attached on the WKA-3. In addition, the doctor subjects also gave the variable opinions that the WKA-3 could not reproduce the infinite compliance coefficient. Moreover, the motion of the tongue and the mandible are far from the real human. For the purpose of this, the author will propose new mechanism which can attach the external and internal organs on the system in the chapter five. Using new mechanism, the author also presents how to reproduce infinite compliance coefficient. Finally, the author will compare the conventional training system with the innovative training system on the simulation of real motion of the patient such as tongue motion and mandible motion. Finally, the author will compare the conventional training system with the innovative training system on the training effectiveness through the learning curve.

1.5.5 Chapter 5

In this chapter five, the author establishes the design methodology for the innovative training system for the airway management using the WKA-4 which fullfil the requirements of the innovative training system. For this reason, the author verifies the effectiveness of each of the requirements of the innovative training system. For this purpose, the author proposes methods for the devleopement of the training system as follows.

1) Propose new mechanism which enables the WKA-1R, WKA-2, and WKA-3 to be integrated into the one system, and can simulate high fidelity of the human anatomy.
2) Propose control system for the various patient patterns such as airway difficulties, individual differences, and simulation of the stiffness of the human's muscles (fuction of the WKA-2), and for the *Patient Scenario* (fuction of the WKA-3)
3) Propose an evaluation function which can evaluate trainee's performance of the task (fuction of the WKA-1R)
4) Compare the training effeciveness between the conventional training system and the innovative training system

For the proposed first method, the author proposed link drive mechanism, wire driving mechanism, and slide screw which can reproduce various patient patters such as airway difficulties, and individual differences, and the four kinds of sensor systems are embedded into the parts of the redesigned organs of the patient model. For the proposed second method, the author proposes control sysem in order to simulate various ranges of the human's muscles same as the author applied the *Virtual Compliance Control* in the chapter four, and to reproduce the *Patient Scenario Generation* for real world condition of the task same as the author applied it in the chapter four. For the proposed third method, the author propose an evaluation function to provide objective assessment of the trainee's performance while performing the airway management, and in order to determine weigh coefficients of evaluation function, the author applied discriminant analysis same as the author applied them in the chapter two. For the proposed third method, the author compares the training effeciveness between the conventional training system and the innovative training system in order to verify the effectiveness of the proposed innovative training system.

In order to verify the effectiveness of the proposed methods, four experiments have been carried out. From the result of the first experiment, WKA-4 not only satisfies the reproduction of the airway difficulties and the human body, but also establishes high fidelity of the human anatomy as a training system. Therefore, the author verified the effectiveness of the proposed new mechanism. From the result of the second experiment, the author verified the effectivenss of the proposed control system for the simulation of the stiffness of the human's muscles, and the reproduction of the proposed *Patient Scenario Algorithm* using actuators and sensors same as the previous training system WKA-3. From the result of the third experiment, the author confirmed and established the way to provide quantitative information of the trainee's performance of the tasks to trainee while performing airway management, and objective assessmen using the sensor systems same as the previous training system WKA-1R. From the result of the fourth experiment, the author verified that proposed innovative training system has better training effectiveness than the conventional training system through the learning curve.

1.5.6 Chapter 6

In the chapter six, the author presents the conclusion and the future works such as the possibility of using the proposed innovative medical training system in the other fields of medical training, and present the possibility of the commercialization.

Chapter 2

Provision of Useful Feedback and Objective Assessment of Training Progress

2.1 Purpose: Provision of Useful Feedback and Objective Assessment of Training Progress

As shown in Fig. 1.9, the inovative training system should fulfill four requirements: 1) provide useful feedback to trainees and objective assessments of training progress, 2) reproduce the various patient patterns, 3) reproduce *Patient Scenario* for real-world conditions of the task and adjust degree of difficulty for trainee's effective training, and 4) simulate high-fidelity simulated human anatomy as shown in Fig 1.9.

As shown in Fig. 1.9, the innovative training system consists of a high fidelity simulated patient model, sensor system, objective evaluation unit, various patient patterns, and *Patient Scenario Generation*. While the trainee is trained with high fidelity simulated patient model, the sensors of the patient model obtain the quantitiave information of the

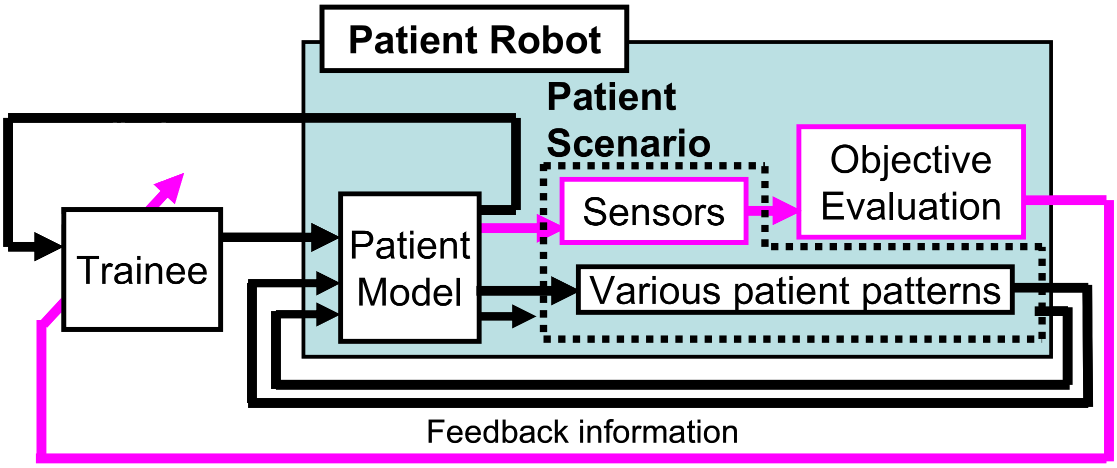


Figure 2.1: Characterisitc of Waseda KyotoKagaku Airway No.1 (WKA-1) (purple line)

trainee's performance. The evaluation unit evaluates the trainee's performance from the obtained quantitative information. The evaluation system provides feed back information to the trainee. From this feed back information, the trainee can understand their performances better. In addition, the unit of various patient patterns can simulate the various pattern patients, and the unit of *Patient Scenario Generation* can simulate real world condition of the real patients which can simulate static or dynamic patient characteristics. At this time, the trainee can cope with the various situations of the patients such as airway difficulties, various individual differences, and this *Patient Scenario Generation* can adjust degree of difficulty for the trainee's effective training. Without the supervisor, the author expects that the trainee can improve their performance of the task.

In order to achieve the concept of the effective innovative training system, as a first step of the innovative training system, the author establishes a way to provide quantitative information of the trainee's performance of the tasks to trainee while performing airway management, and provide objective assessment (Figure 2.1). For the purpose of these facts, the author is proposing the WKA-1R (Waseda Kyotokagaku Airway No.1 Refined) which has embedded sensor systems to obtain quantitative information of trainee performance. The WKA-1R has sensor systems such as FDSS (Force Detection Sensor System), PDSS (Position Detection Sensor System), and DDSS (Displacement Detection Sensor System) which can measure the quantitative information of the trainee's performance of the task.

For this WKA-1R, the author proposes methods for the developement of the training system as follows.

1. Propose sensor systems and WKA-1R in order to obtain quantitative information of the trainee's performance of the task while performing the airway management
2. Propose an evaluation function to provide objective assessment of the trainee's performance while performing the airway management

A set of the experiments have been carried out in order to verify the effectiveness of the proposed methods

2.2 Method

2.2.1 Propose Sensor Systems and WKA-1R in order to Obtain Quantitative Information of the Trainee's Performance of the Task while Performing the Airway Management

A) Procedures of Airway Management and Principle of Sensor Systems

Basically, the procedure of airway management consists of six main steps [67][68]:

- 1st Step: Setting of the sniffing position
- 2nd Step: Opening mouth and inserting of laryngoscope into the oral cavity
- 3rd Step: Withdrawal of the laryngoscope
- 4th Step: Inserting of endotracheal tube into vocal cord
- 5th Step: Positioning of the endotracheal tube
- 6th Step: Inflating endotracheal tube's cuff on the trachea

The first step of this procedure is the setting of the sniffing position and opening the mouth in order to observe vocal cord through the laryngoscope. From here, the author has identified the inclination of head with respect to the neck, the inclination of lower cervical spine on the chest, and maximum aperture of the mouse as task parameters (Figure 2.2)

The second step of this procedure is the inserting laryngoscope into the oral cavity in order to observe the vocal cord through the laryngoscope. The point is which part of the

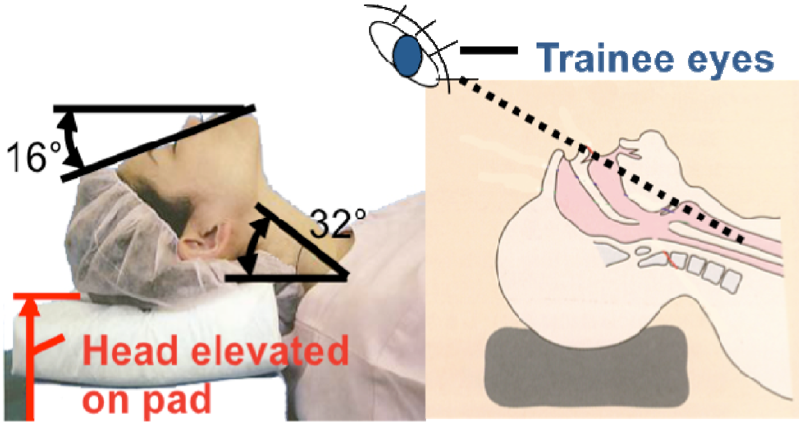


Figure 2.2 First step of airway management: setting of the sniffing position

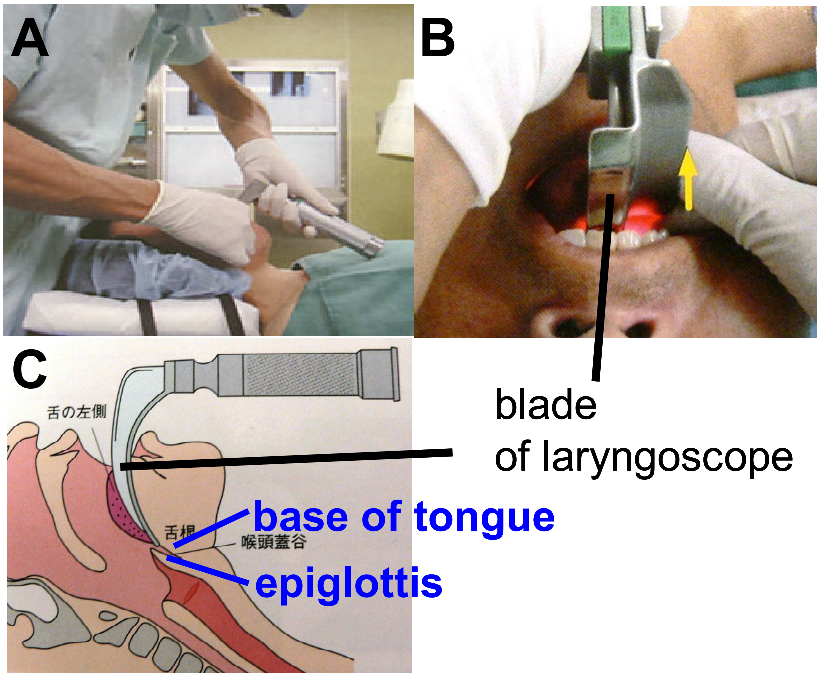


Figure 2.3 Second step of airway management: opening mouth and inserting of laryngoscope into the oral cavity

tongue the blade of laryngoscope is placed on, and the applied force on that part of the tongue (Figure 2.3).

The third step of this procedure is the withdrawal of the laryngoscope in order to observe vocal cord by pressing the base of the tongue using the laryngoscope. However, operators often press the base of tongue in the wrong way of using the incisor teeth as fulcrum for the blade of laryngoscope or press the epiglottis (Figure 2.4).

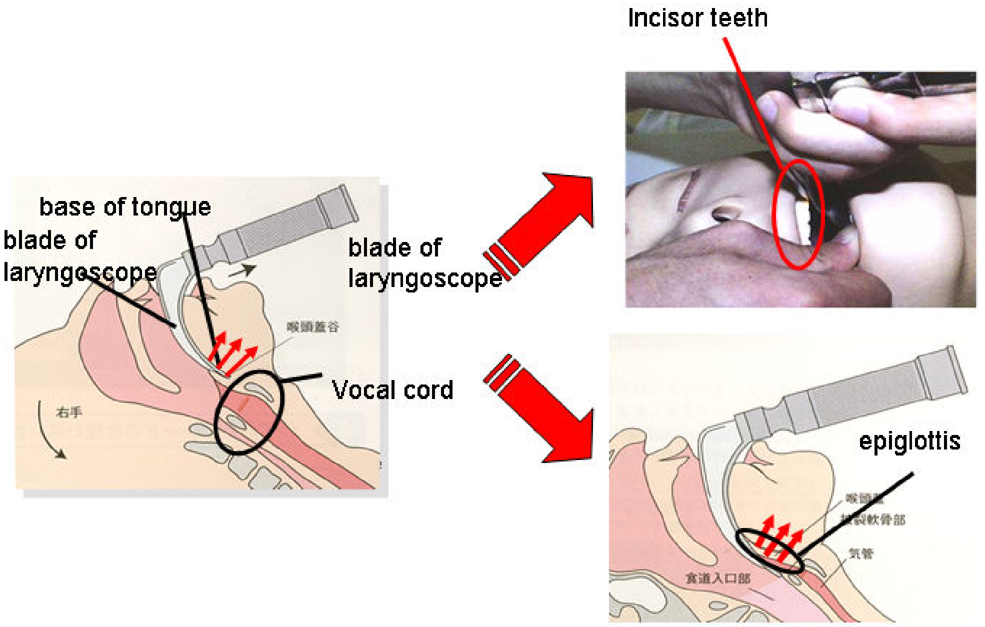


Figure 2.4 Third step of airway management: withdrawal of the laryngoscope

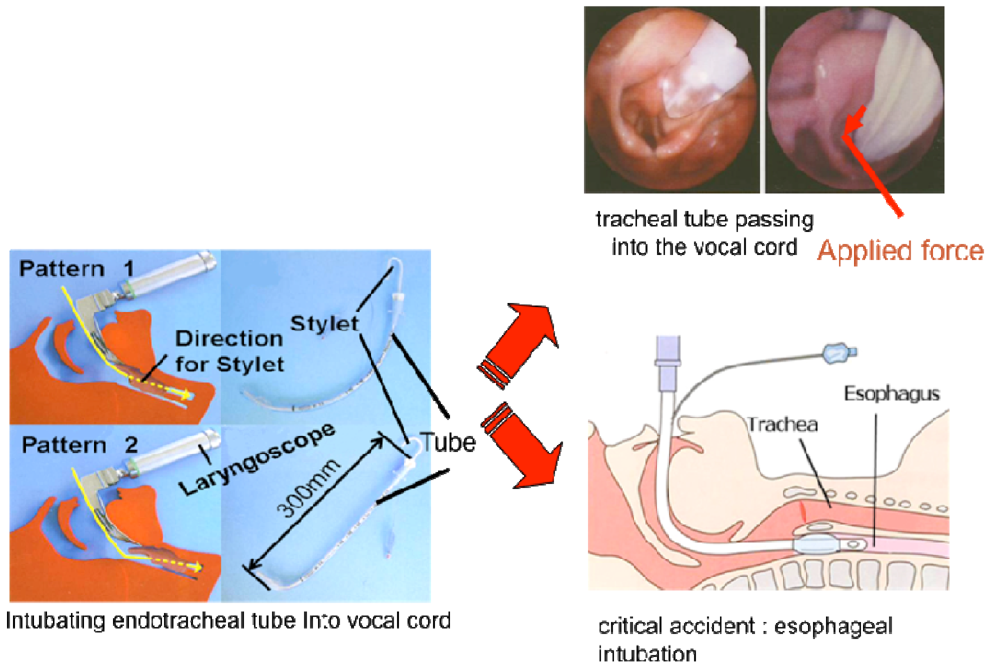


Figure 2.5 Fourth step of airway management: inserting of endotracheal tube into vocal cord

The forth step of this procedure is the intubating endotracheal tube into the vocal cord (Figure 2.5). （according to the vision of vocal cord through the laryngoscope, the tip

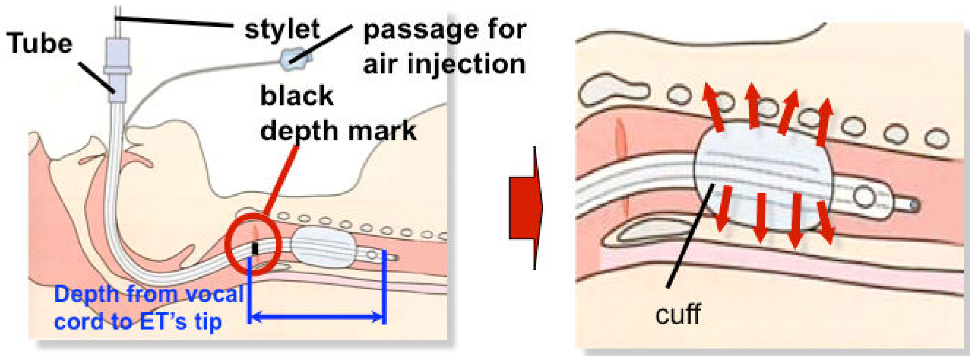


Figure 2.6 Fifth step of airway management: positioning of the endotracheal tube
Sixth Step of airway management: inflating endotracheal tube's cuff on the trachea

deflection of endotracheal tube should be adjusted by inserting a stylet in order for the ET to pass through the vocal cord.)

The fifth step of this procedure is the placing endotracheal tube into the trachea. This procedure is to place the tip of endotracheal tube in the trachea. However, unskilled operators make it positioned in one side of bronchi. Thus, the author identified the position of the tip of endotracheal tube as a task parameter (Figure 2.6).

The sixth step of this procedure is the inflating the cuff of endotracheal tube on the trachea in order to protect the lung from any gastric foreign body. However, inflated cuff may lead to traumatizing the mucous membrane on the trachea (Figure 2.6). For the acquisition of the information of the trainee's performance of the task during the airway management, four kinds of sensors are required as shown in Fig. 2.7.

B) Force Detection Sensor System (FDSS)

The FDSS consists of three layers (Figure 2.9): black elastic sponge, white reflective plastic, and photo interrupter. A small-package photo interrupter which combines a GaAs IRED with a high-sensitivity phototransistor was used. Such sensor presents linear characteristics between 1mm and 3mm (Figure 2.8). These properties are useful for reducing the required space for embedding it into the mannequin [69][70]. The working principle of FDSS is as follows (Figure 2.9): when light is emitted from the GaAs IRED and reflected by the white reflective plastic, the photo transistor collects the reflected light. When the distance between the photo interrupter and the white reflective plastic become closer, the reflected

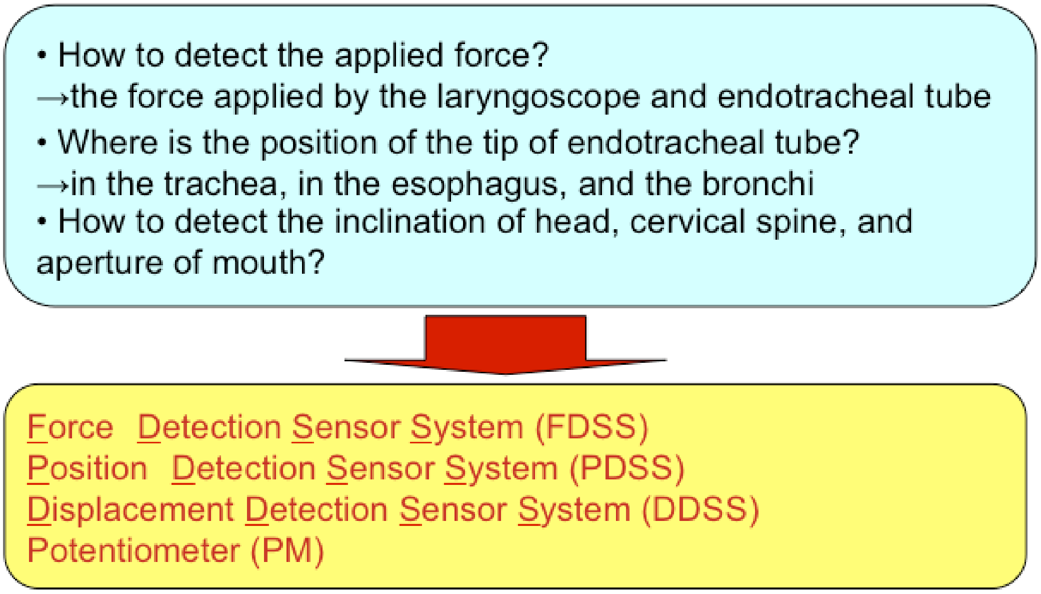


Figure 2.7 Design concept of sensor systems for airway management

light's quantity becomes larger. Thus, the electric current that flows inside the phototransistor will increase in proportion to the reflected light quantity.

C) Improved Force Detection Sensor System (Improved FDSS)

Using the principle of the FDSS, the author also proposes the other FDSS. The improved FDSS of WKA-1R consists of four elements (Figure 2.10): a photo interrupter, white reflective, spring, and spring guide. The principle of the improved FDSS is basically the same as the previous FDSS; however, in order to avoid the non-linear properties of the sponge, a spring material was placed between the photo interrupter and the reflective material. By using such a design, regardless the location of the applied forces on the FDSS, the characteristic curve of the sensor is all but same the same.

D) Position Detection Sensor System (PDSS)

In order to detect the position of an object, it is required the use of one photo interrupter and a black hollow material surrounded (Figure 2.11). At first, when no object is placed in front of the sensor, the black hollow material will absorb the emitted light (no current will flow inside the phototransistor). When any object is placed in front of the sensor,

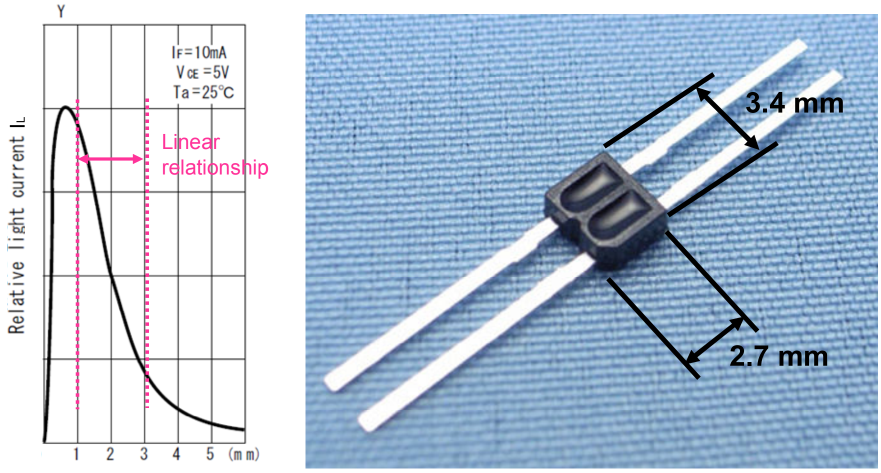


Figure 2.8 Characteristic of photo interrupter

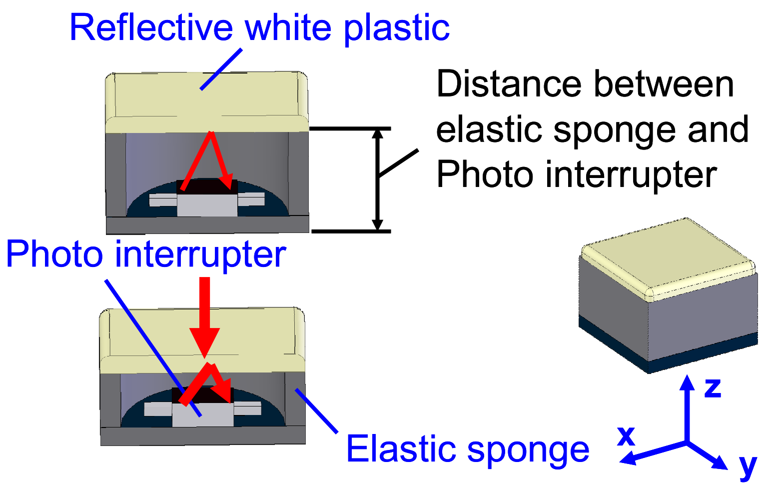


Figure 2.9 Working principle of the Force Detection Sensor System (FDSS)

the emitted light will be reflected so that electric current will flows inside the photo interrupter. Such output current will increase in proportion to the amount of reflected light. By following this principle, for example, the author can embed several PDSS separated by intervals of 8mm along a tube. In order to detect the position of an object that is inserted into the tube, the author should convert the analog output from the PDSS into digital output.

E) Displacement Detection Sensor System (DDSS)

In order to measure the distance between two objects, the author has proposed the design of a Displacement Detection Sensor System (DDSS). The DDSS consists of a reflective elastic material and a photo interrupter (Figure 2.12). The principle of sensor

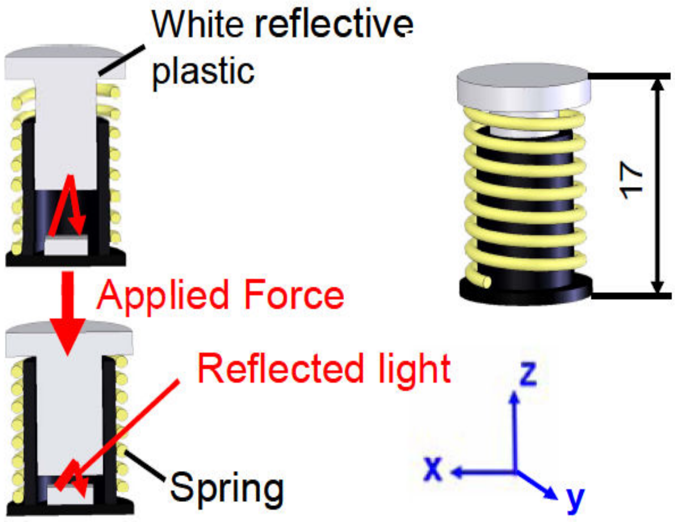


Figure 2.10 Working principle of the improved FDSS

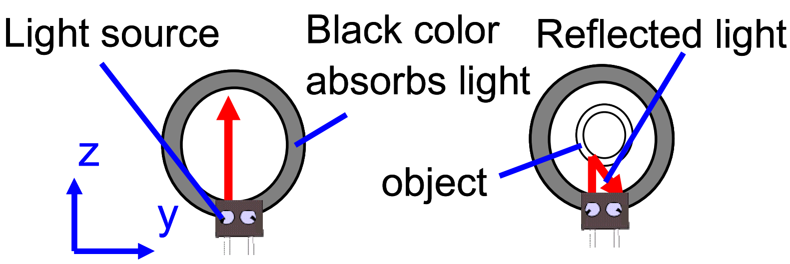


Figure 2.11 Design principle of the Position Detection Sensor System (PDSS)

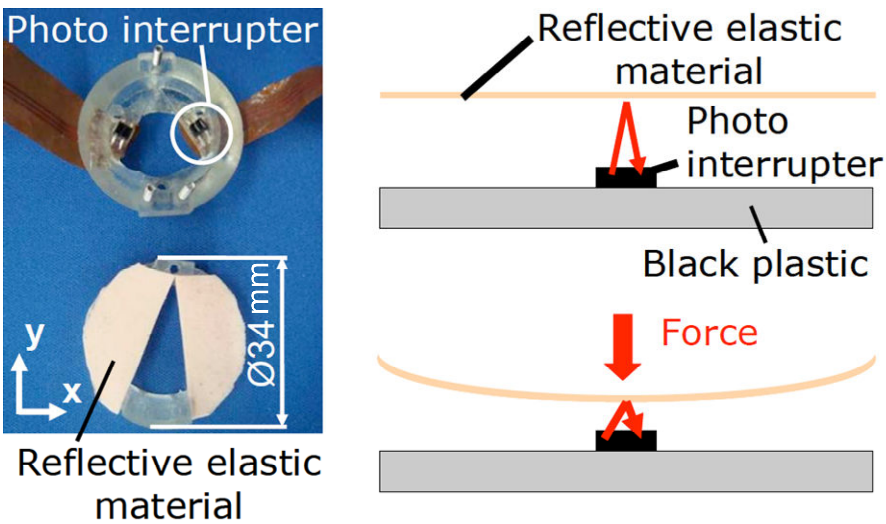


Figure 2.12 Design principle of the Displacement Detection Sensor System (DDSS)

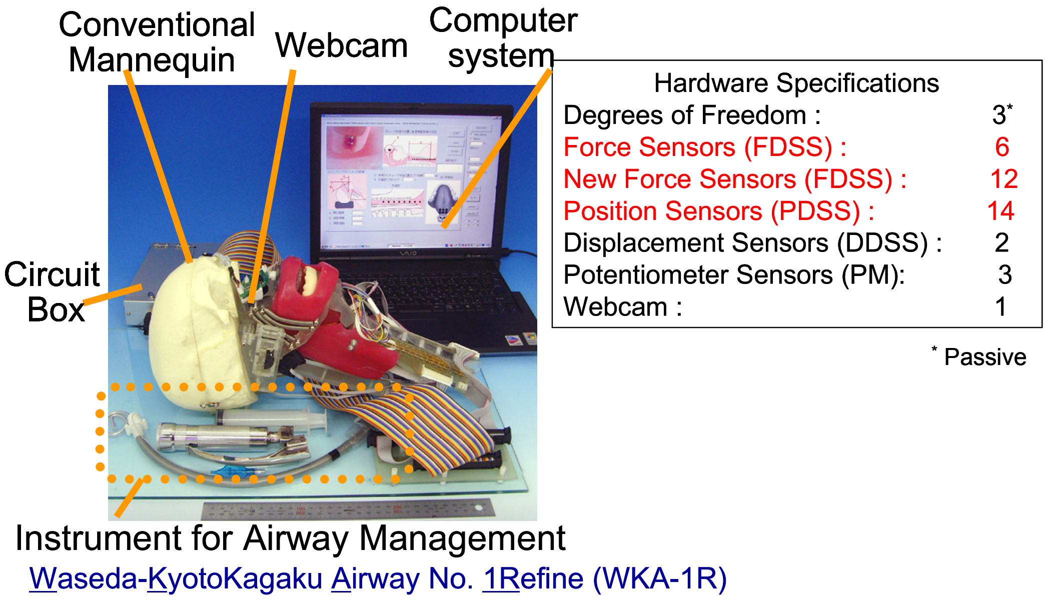


Figure 2.13 System overview of the Waseda Kyotokagaku Airway No.1R (WKA-1R)

system is similar to that of FDSS. The DDSS uses as reflective elastic material an artificial elastic skin (the artificial elastic skin was developed by Kyoto Kagaku Co. Ltd.) which has been applied in a suture training system [34].

F) WKA-1R (Waseda Kyotokagaku Airway No.1Refined)

The proposed WKA-1R consists of a conventional mannequin, a computer system and it is composed by seven main parts such as: head, neck, chest, incisor teeth, tongue, vocal cord, web-cam (Figure 2.13). The design of such simulated organs has been simplified to facilitate the placement of the proposed array of sensors (Figure 2.14). Each of the simulated organs is involved with the airway management procedure, as it was detailed in [41]. The design of most of the parts of the conventional mannequin was simplified in order to embed the FDSS, improved FDSS, PDSS and DDSS. The inner skins of the WKA-1R were developed by Kyoto Kagaku Co. Ltd. (which is a company specializing in professional medical simulators, ultra sound phantoms). The inner skins are: upper trachea, vocal cord, epiglottis, tongue, and esophagus. All the information from the embedded sensors was acquired using an AD converter made by CONTEC. Such converter is connected to a personal computer (sampled at 25 Hz). In addition, a webcam was connected to the personal computer in order to capture the performance of trainee (Figure 2.15). Moreover, the personal

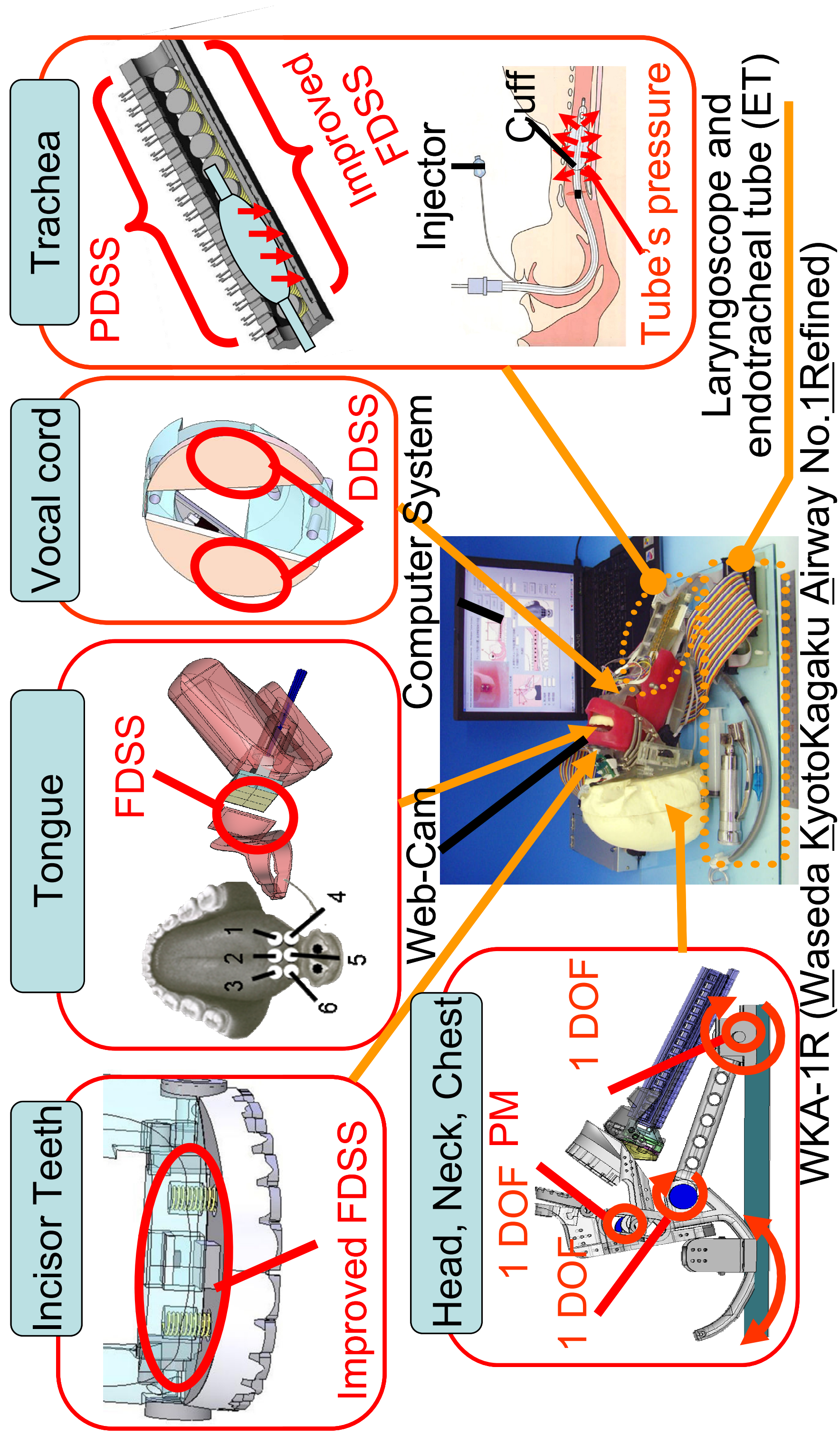
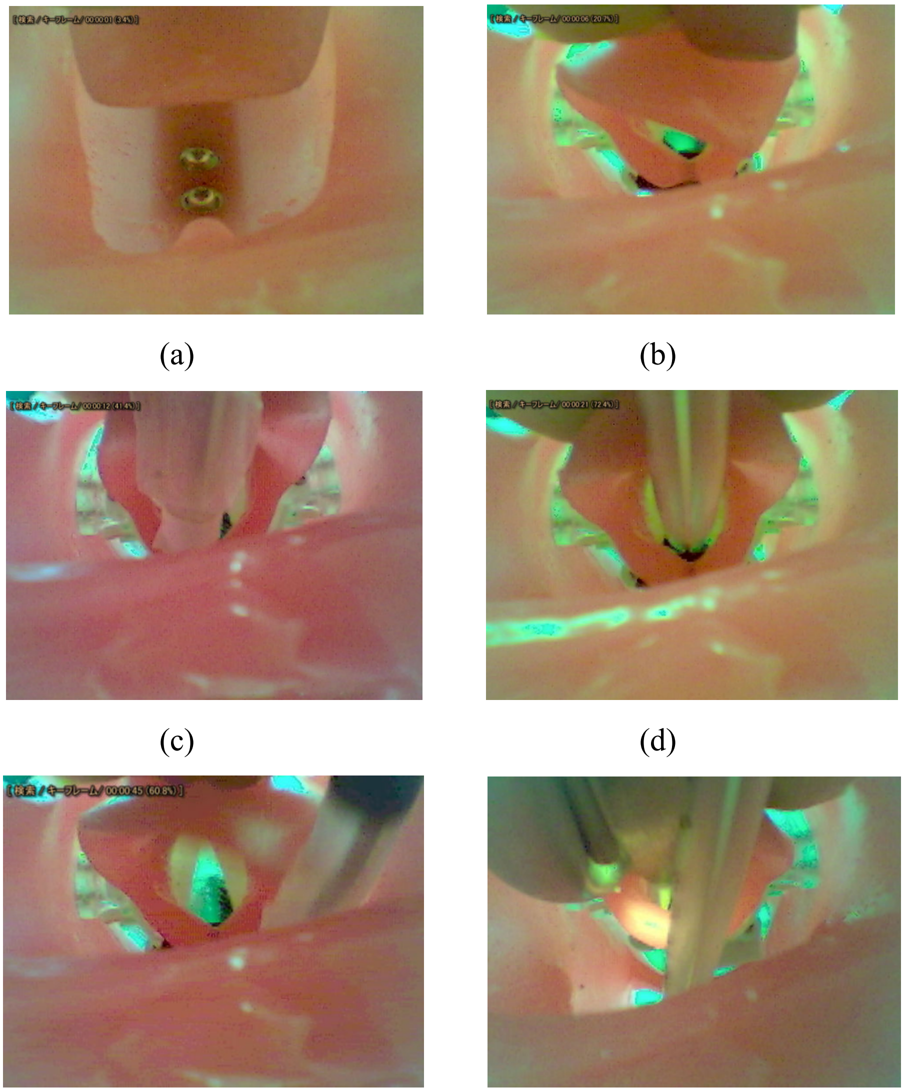


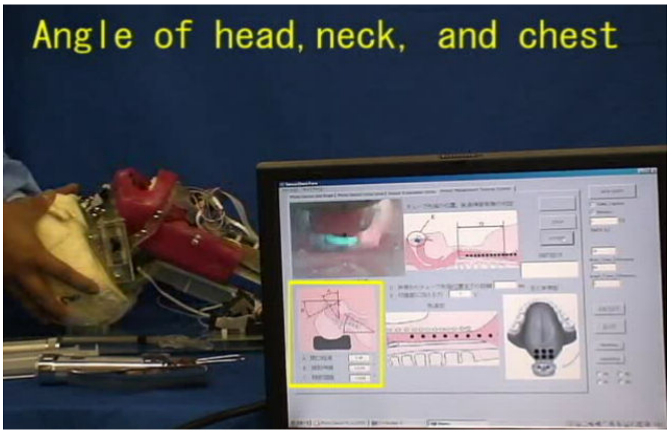
Figure 2.14 Components of the conventional mannequin designed for the WKA-1R: (a) head with embedded potentiometers, (b) incisor teeth with an embedded improved FDSS, (c) tongue with an embedded FDSS, (d) vocal cord with embedded DDSS, and (e) trachea with embedded improved FDSS and PDSS



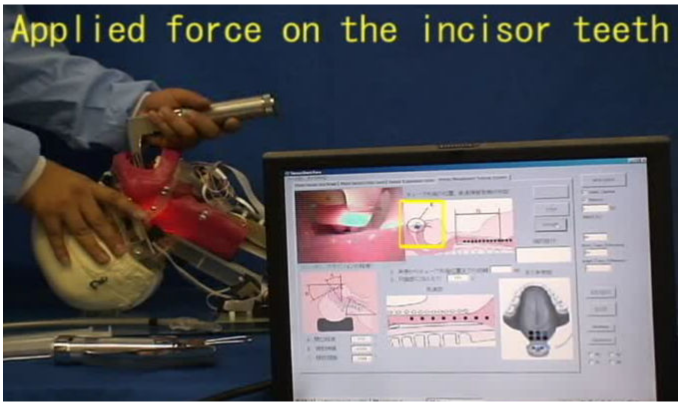
(a) (b) (c) (d) (e) (f)

Figure 2.15 Capturing the performance of trainee with webcam:
(a) 1st Step: Setting of the sniffing position, (b) 2nd Step: Opening mouth and inserting of laryngoscope into the oral cavity, (c) and (d) 4th Step: Inserting of endotracheal tube into vocal cord (e) and (f) Esophageal intubation

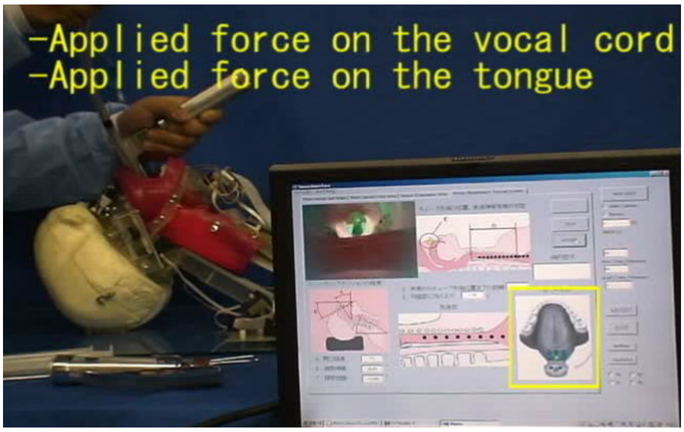
computer includes GUI software modules which can make the trainees understand their performance of the task easily (Figure 2.16-2.17).



(a)



(b)



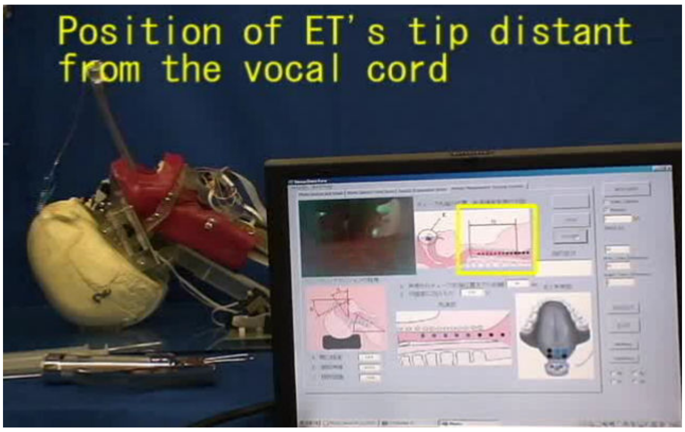
(c)

Figure 2.16 GUI Interface software for WKA-1R

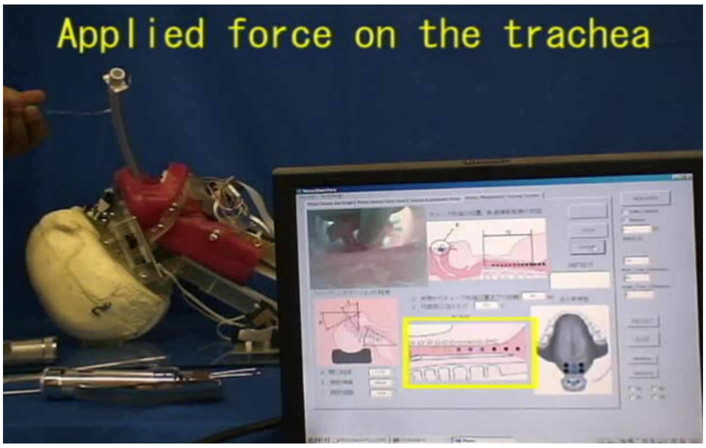
(a) Acqusition of angles of opening mouth, rotating neck, and rotating chest,

(b) Acqusition of the applied force on the incisor teeth

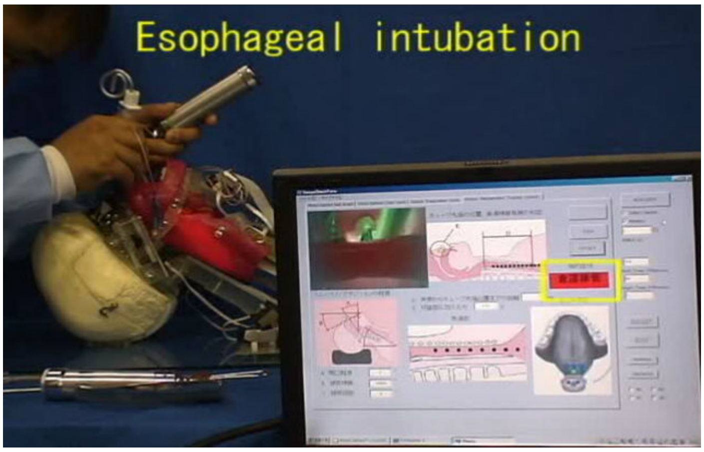
(c) Acquisition of the applied force on the tongue



(a)



(b)



(c)

Figure 2.17 GUI Interface software for WKA-1R

(a) Acqusition of the position of the tip of the endotracheal tube

(b) Acqusition of the applied pressure on the trachea

(c) Acquisition of the esophageal intubation

2.2.2 Propose an Evaluation Function to Provide Objective Assessment of the Trainee's Performance while Performing the Airway Management

A) Determination of Performance Index (PI)

From the evaluation parameters, the following performance indexes were defined as it is shown in Table 2.1. These indexes are normalized by defined threshold values which are average data of unskilled subjects and anesthetists, or the clinical data referred to the medical literatures.

B) Evaluation Function

There are many evaluation ways for airway management skill such as airway skill checklists [76][77]. However, these evaluation ways have many problems: First, instructors observe trainee's skill, they only checked 'Pass' or 'Fail', subjectively without any kinds of quantitative information of trainee's skill, no scoring is trainee's performance. In order to understand better the training progress of trainees, the author has proposed an evaluation function; as it is shown in Eq. 2.1. Evaluation function consists of six performance indexes and 6 weighting coefficients. Each of the performance indexes indicates quantitative information of operator's skill which enables trainee to recognize their bad habits and good skills, and each of weighing coefficients can score trainee's skill which can provide learning curve and better understanding of their progress of skill. In this section, the author will define each of performance indexes, and state how they are normalized applying the threshold value average data of unskilled subjects and anesthetists, or the clinical data referred to the medical science paper, and medical text book.

Table 2.1 Proposed Evaluation Paramenters

Symbol	Evaluation Parameter
InT	Intubation Time
JaO	Jaw Opening
InF	Incisor Teeth's Force
CPr	Cuff's Pressure
ToF	Tongue's Force
TuP	Tube's Position

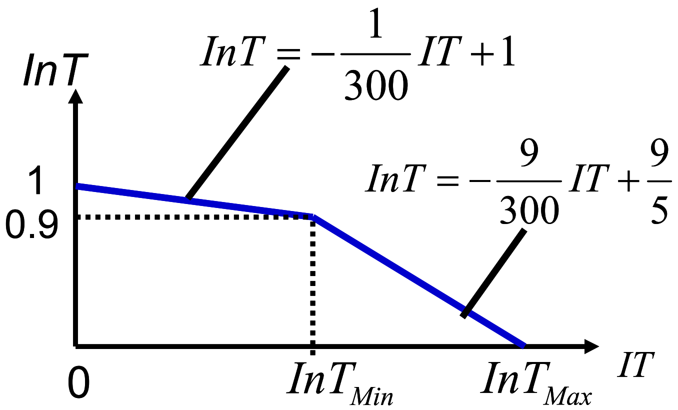


Figure 2.18 Definition of Performance Index : *Intubation Time Index* (*InT*)

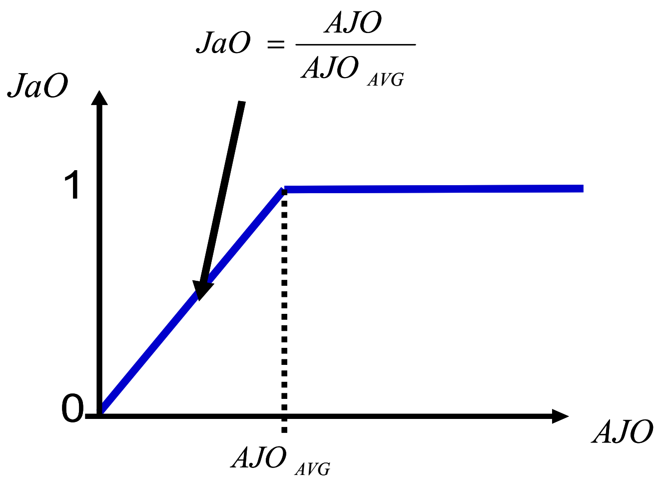


Figure 2.19 Definition of Performance Index: *Jaw Openg* (*JaO*)

In the following paragraphs, each of the evaluation parameters of the proposed evaluation function are detailed as follows.

$$E_{airway} = w_{InT} \cdot InT + w_{JaO} \cdot JaO + w_{InF} \cdot InF + w_{C\,\mathrm{Pr}} \cdot C\,\mathrm{Pr} + w_{ToF} \cdot ToF + w_{TuP} \cdot TuP \qquad (2.1)$$

1) Intubation Time Index (*InT*): it indicates the normalized quantity which operators spend on performing the six steps of airway management. The author defines *Intubation Time* (*IT*) as the time that is required to perform the six steps of airway management as it is shown in Eq. 2.2 (where IT_{MIN} = 30 and IT_{MAX} =60). The medical literature states that standard intubation time (IT_{MIN}) is less than 30sec (it would be optimal to perform the tracheal intubation as fast as

$$IntT = \begin{cases} -\frac{1}{300} IT + 1, & 0 < \mathrm{IT} \le \mathrm{IT}_{\mathrm{MIN}} \\ -\frac{9}{300} IT + \frac{9}{5}, & \mathrm{IT}_{\mathrm{MIN}} < \mathrm{IT} \le \mathrm{IT}_{\mathrm{MAX}} \\ 0, & 60 < \mathrm{IT}_{\mathrm{MAX}} \end{cases} \tag{2.2}$$

$$\mathrm{JaO} = \begin{cases} \frac{AJO}{AJO_{AVG}}, & 0 < AJO \le AJO_{\mathrm{AVG}} \\ 1, & \mathrm{AJO}_{\mathrm{AVG}} < AJO \end{cases} \tag{2.3}$$

possible), and *failed Intubation Time* (IT_{MAX})is greater than 60 sec due to a lack of oxygen to the brain [75] (Figure 2.18).

2) Jaw opening index (*JaO*): it indicates the normalized quantity which is the angle of opening mouth (*AJO*). The author defined the *angle of Opening mouth (AJO)* as the rotated angle with respect to the potentiometer (*PM*) embedding the part of jaw; as it is shown in Eq. 2.3. The medical literature states that standard aperture of the mouth is greater than 5cm [78]. In Eq. 2.3, AJO_{AVE} = 12.6 degrees is experimentally defined by measuring the angle of aperture of the mouth (Figure 2.19).

$$InF = w_{int} InF_{int} + w_{max} InF_{max} \tag{2.4}$$

$$IncT = \int_{0}^{\mathrm{IT}} V(t)_i \, dt \tag{2.5}$$

$$InF_{int} = \begin{cases} 1 - \frac{IncT}{IncT_{MAX}}, & 0 < \mathrm{IncT} \le \mathrm{IncT}_{\mathrm{MAX}} \\ 0, & \mathrm{IncT}_{\mathrm{MAX}} < \mathrm{IncT} \end{cases} \tag{2.6}$$

$$InF_{max} = \begin{cases} 1 - \frac{IncM}{IncM_{MAX}}, & 0 < \mathrm{IncM} \le \mathrm{IncM}_{\mathrm{MAX}} \\ 0, & \mathrm{IncM}_{\mathrm{MAX}} \le \mathrm{IncM} \end{cases} \tag{2.7}$$

3) Incisor Teeth's Force (*InF*): it indicates the normalized quantity of applied force on the incisor teeth. It consists of two indexes such as applied integral force index (InF_{int}) and applied maximum force index (InF_{max}) as it is shown in Eq. 2.4. Applied integral force index (InF_{int}) indicates the normalized quantity which is the integral of the applied force over the entire time. The author defines Voltage-Time Integral of Incisor Teeth (*IncT*) as the integral of the applied force over the entire time as it is shown in Eq. 2.5. The medical literature states that it would be optimal not to apply the force on the incisor teeth by the laryngoscope (Figure 2.21). Therefore, the author can measure the extent of the damage of incisor teeth utilizing the Eq. 2.6. *Applied Maximum force index* (InF_{MAX}) indicates the normalized quantity which is the applied maximum force on the incisor teeth as it is shown in Eq. 2.7 and Fig. 2.20. The author defined *Maximum applied force on incisor Teeth* (*IncM*) as the Maximum force over the entire time. The medical literature states that incisor teeth break approximately 200N to 400N [79]. Therefore, $IncM_{MAX}$ =200; the author can measure the degree of the damage of incisor teeth utilizing the Eq. 2.7.

4) *Tongue's Force* (*ToF*): it indicates the quantity which is applied force on the tongue by the laryngoscope (this index is related to step three). It consists of four indexes such as applied integral force index ($ToF_{sensor}[n]$) which is applied force on each of the FDSSs embedding the tongue as it is shown in Eq. 2.8. The author defined the applied force on tongue ($V_{sensor}[n]$) as the applied force on each of the FDSSs embedding the tongue at the moment that endotracheal tube is passed into the vocal cord. From the first and second experiment result, the author found the measured average voltages of anesthetist group ($V_{MAX}[n]$ where, n = 1, 2, 4, 5) on the FDSSs #1, #2, #4, and #5 which are embedded into the tongue are greater that average voltages of unskilled subject group ($V_{MIN}[n]$ where, n = 1, 2, 4, 5). Therefore, substituting $V_{MAX}[n]$ and $V_{MIN}[n]$ into the Eq. 2.9 as shown in Fig. 2.22; the author can measure the degree of the opening epiglottis.

5) *Cuff's Pressure* (*CRr*): it indicates the normalized quantity of applied pressure on the trachea by the tube's cuff. This index is related to step six. As it was previously stated, the author found the relationship between the pressure and the sum of each of the applied force on the FDSSs as it is shown in Eq. 2.10. Medical literature classifies 4 levels such as weak ($0< P_{cuff} <20$), proper ($20 < P_{cuff} <30$), strong ($30 < P_{cuff} <40$), and critically strong pressure ($40 < P_{cuff}$) according to the applied pressure, where the unit of P_{cuff} is cmH_2O as shown in Fig. 2.23 [80]. Referring the Eq. 2.10; the author calibrate the relationship between Pcuff and Fcuff as it

is shown in Eq. 2.10. Therefore, the author can measure the degree of the damage of trachea utilizing the following equation.

$$ToF = w_{TOF1}\sum_{n=1}^{2} ToF_{sensor}[n] + w_{TOF2}\sum_{n=4}^{5} ToF_{sensor}[n] \tag{2.8}$$

$$ToF_{Sensor}[n] = \begin{cases} 0, & \mathrm{V_{MIN}}[n] < ToF_{\mathrm{Sensor}}[n] \\ \dfrac{V_{sensor}[n]-V_{MIN}[n]}{V_{MAX}[n]-V_{MIN}[n]}, & \mathrm{V_{MIN}}[n] < ToF_{Sensor[n]} < V_{MAX}[n] \\ 1, & \mathrm{V_{MAX}}[n] < ToF_{Sensor[n]} < V_{MAX}[n] \end{cases} \tag{2.9}$$

6) *Tube's Position* (*TuP*): it indicates the normalized quantity of the tip of endotracheal tube. From the medical literature, it states that human trachea length, which is distance from the vocal cord, is approximately 120-130 [mm], so in order to position the endotracheal tube in the trachea, tube's position which is distant from the vocal cord is less than 120-130 [mm] [78]. Therefore, In order to normalize TuP, the author consider three cases such as tracheal intubation, bronchial intubation, and esophageal intubation as it is shown in Eq. 2.11. According to the tip position of endotracheal tube (*D*), the author can measure the extent of tube's position utilizing the follow equation.

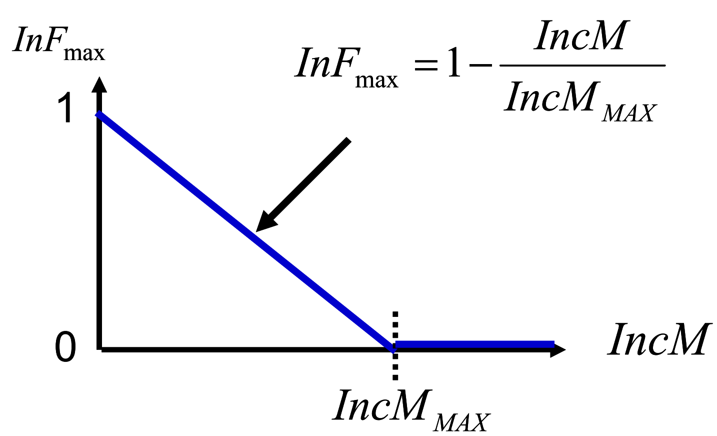
$$CPr = \begin{cases} \dfrac{\mathrm{F_{cuff}}}{1.8}, & 0 < \mathrm{F_{cuff}} < 1.8[N] \rightarrow 0 < \mathrm{P_{cuff}} < 20[cmH_2O] \\ 1, & 1.8 < \mathrm{F_{cuff}} < 3.0[N] \rightarrow 20 < \mathrm{P_{cuff}} < 30[cmH_2O] \\ -\dfrac{10}{7}F_{cuff} + \dfrac{44}{7}, & 3.0 < \mathrm{F_{cuff}} < 3.7[N] \rightarrow 30 < \mathrm{P_{cuff}} < 40[cmH_2O] \\ 0, & 3.7 < \mathrm{F_{cuff}} \rightarrow 40 < \mathrm{P_{cuff}}[cmH_2O] \end{cases} \tag{2.10}$$

$$TuP = \begin{cases} 0, & \mathrm{D} = 0 \\ 0.5, & 120 < \mathrm{D} \\ 1, & 0 < \mathrm{D} < 120 \end{cases} \tag{2.11}$$

C) Discriminant Analysis

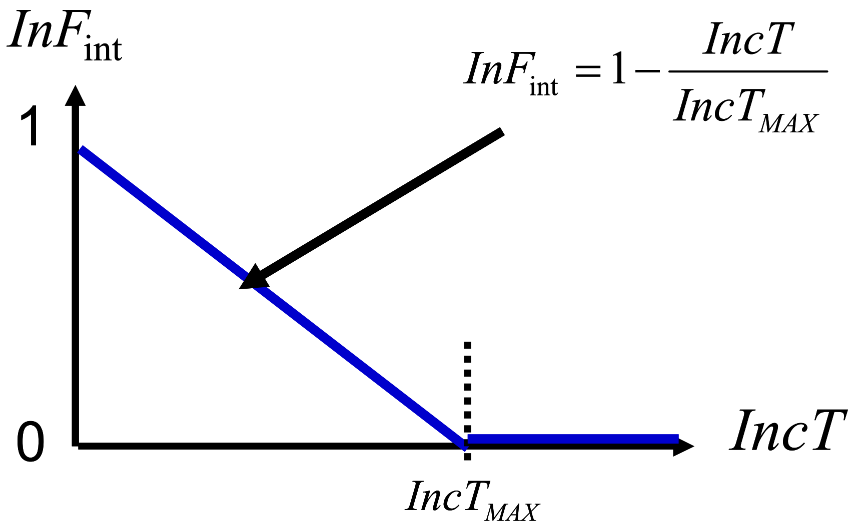
In the present, there are many scientific methodologies such as Least Square, Genetic Algorithm, Neural Network, and Hidden Markov Model to determine weighting coefficients. In medical field, there are no such scientific methodologies in order to determine weighting coefficients because among doctors there are differences on skills, there are different ways to perform medical operation according to doctors, and human performance is stochastic nature. In addition, in order to apply such scientific methodologies, a lot of data are required. Therefore, as a first approach, the author used discriminant analysis in order to determine the weighting coefficients of evaluation function. A linear discriminant equation (Eq. 2.12) is constructed such that the two groups differ as much as possible on D (X represents the proposed evaluation parameters) [81]. That is, the weights are chosen so that were you to compute a discriminant score (Di) for each subject and then do an ANOVA on D, the ratio of the between groups sum of squares to the within groups sum of squares is as large as possible. The author applied the discriminant analysis

$$D_i = a + b_1 X_1 + b_2 X_2 + \cdots + b_P X_P \qquad (2.12)$$



IncM : Maximum applied force on incisor Teeth
$IncM_{MAX}$: Threshold maximum force on the incisor Teeth

Figure 2.20 Definition of Performance Index: *Incisor Teeth's Force*: *Applied Maximum Force Index*



$IncM$: Maximum applied force on incisor Teeth

$IncM_{MAX}$: Threshold maximum force on the incisor Teeth

Figure 2.21 Definition of Performance Index: *Incisor Teeth's Force*: *Applied Integral Force Index*

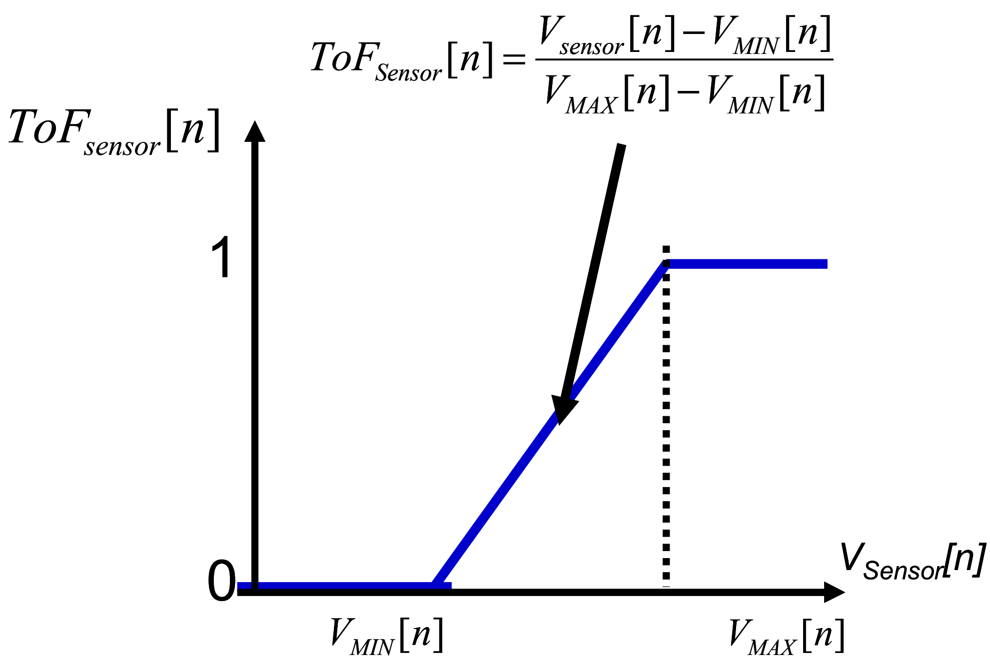


Figure 2.22 Definition of Performance Index: *Tongue's Force Index*

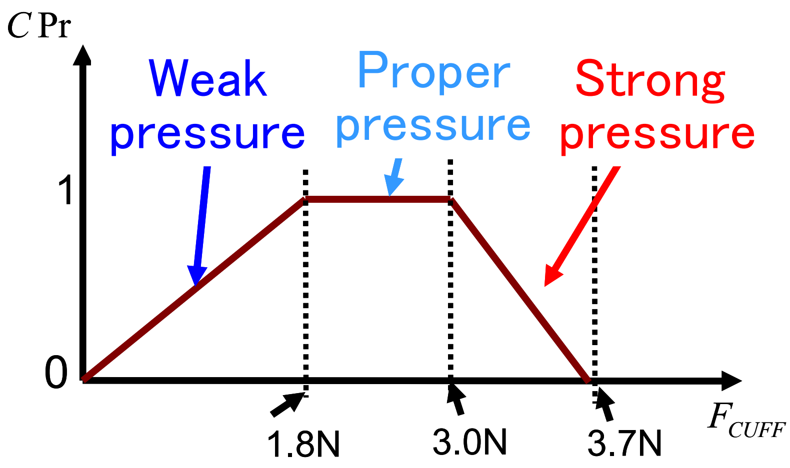


Figure 2.23 Definition of Performance Index: *Cuff's Pressure Index*

2.3 Results

2.3.1 Verification of Proposed Sensor Systems and WKA-1R in order to Obtain Quantitative Information of the Trainee's Performance of the Task while Performing the Airway Management

A) Characterisitic Curve of the Proposed Sensor Systems

The relation between the output voltage and the applied force was obtained by using an experimental device developed at Waseda University. The experimental device is composed by 1-DOF actuated by a DC motor (Figure 2.24). The actuated mechanism was designed to apply pressure on the elastic sponge along the Z-axis. The applied force was registered by attaching a load cell to the end-effector (Figure 2.24, left). The output characteristics of the PDSS were obtained again by design an experimental device (Figure 2.24: right). The experimental device is also composed by 1-DOF actuated by a DC motor. In order to measure the characteristic output of the PDSS, the author has attached a link at the end-effector. By using the actuation mechanism, the link can be controlled to be inserted into

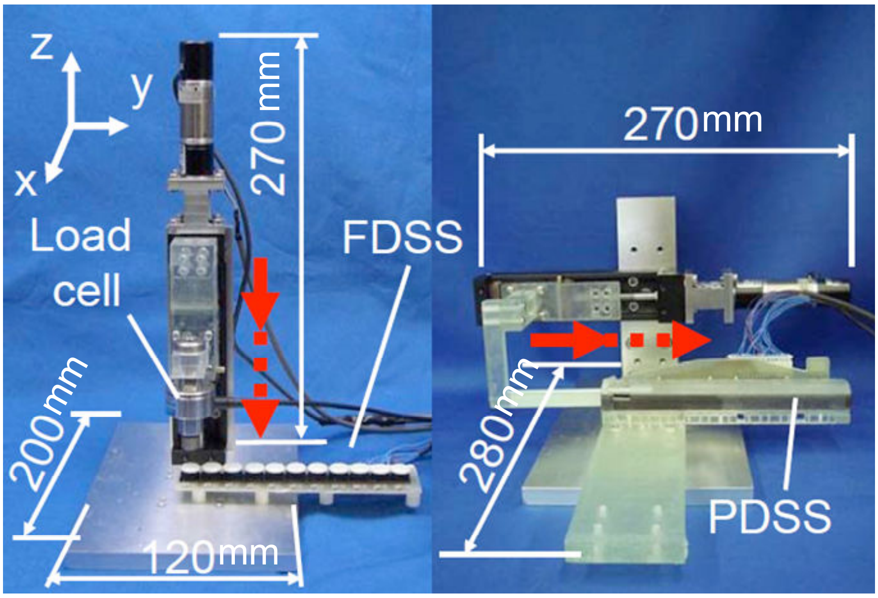


Figure 2.24 Detail of the experimental device used to determine the characteristics of the proposed arrays of sensors

the tube. The data obtained from the PDSS was also processed using an A/D converter from CONTEC.

By measuring the measured force (an A/D converter from CONTEC was used with a maximum conversion speed of 40ms) from the load cell and the output voltage from the photo interrupter, the author obtained the characteristic response of the proposed FDSS (Figure 2.25). The linear response of the sensor was observed between 0 to 2.7 volts. Depending on the sponge's elastic coefficient, the author can modify the desired range of force. It can fit in 3rd order curve, and it is all but close to a linear curve.

By measuring the measured force (an A/D converter from CONTEC was used with a maximum conversion speed of 40ms) from the load cell and the output voltage from the photo interrupter, the author obtained the characteristic response of the proposed improved FDSS (Figure 2.26). The characteristic curve can be fitted by the 4th order curve response of the sensor was observed between 0 to 3.25 volts. Depending on the spring's elastic coefficient, the author can modify the desired range of force.

The output characteristics of the DDSS are shown in Fig. 2.27. As the author can observe, the displacement of the detected object will be proportional to the output voltage of the photo interrupter. In proportion to the applied force on the DDSS, displacement

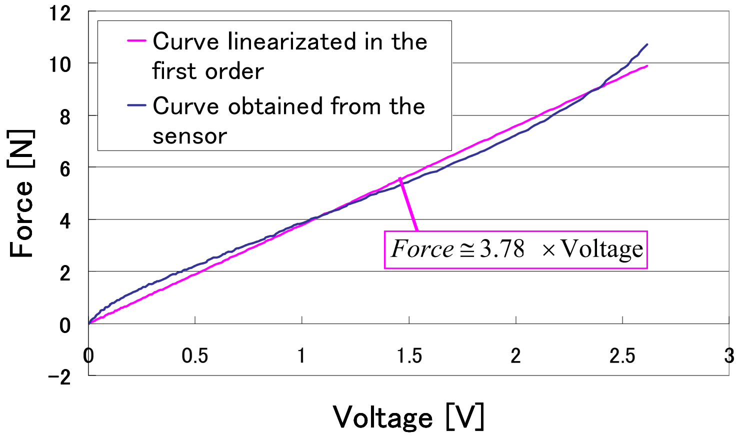


Figure 2.25 Characteristic response curve of the proposed FDSS obtained by applying force along the Z-axis using an experimental device

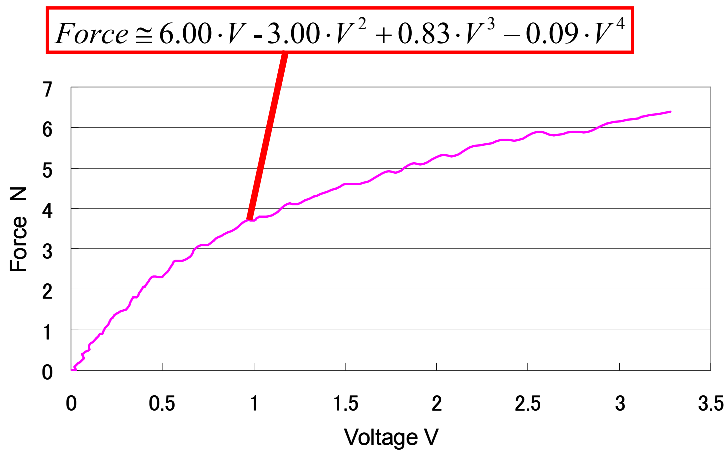


Figure 2.26 Characteristic response curve of the proposed improved FDSS obtained by applying force along the Z-axis using an experimental device

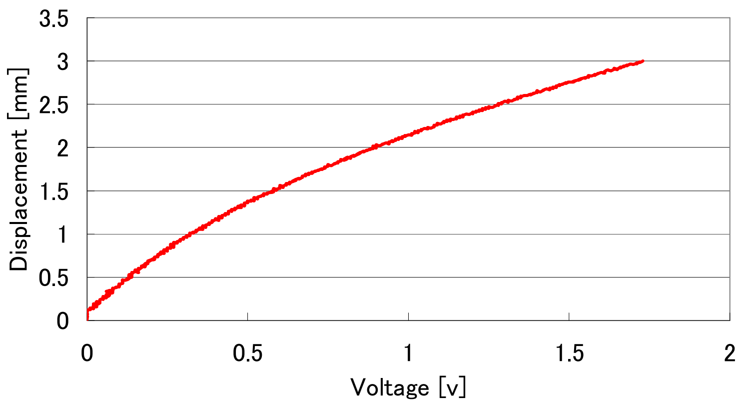


Figure 2.27 Characteristic output from the proposed DDSS.

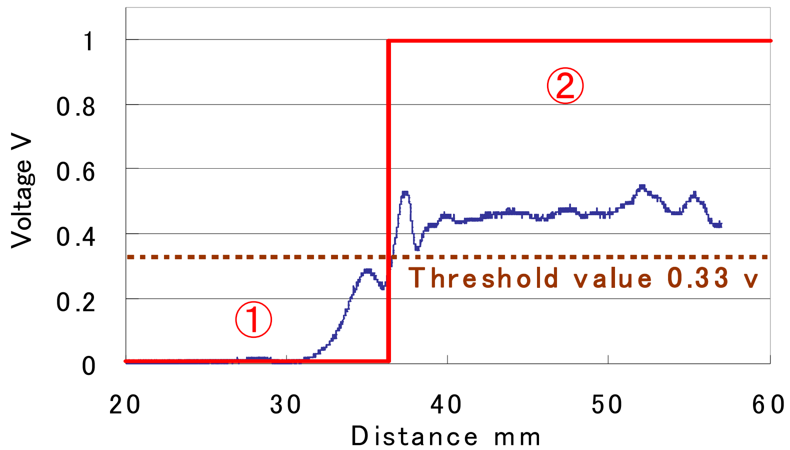


Figure 2.28 Characteristic output from the proposed PDSS obtained by using developed experimental device.

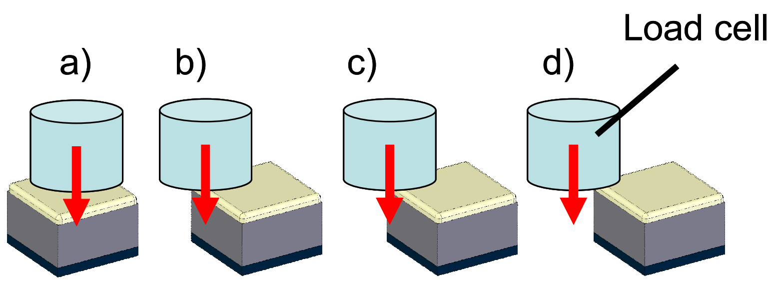


Figure 2.29 Experimental conditions to determine the curve characteristics of the proposed FDSS

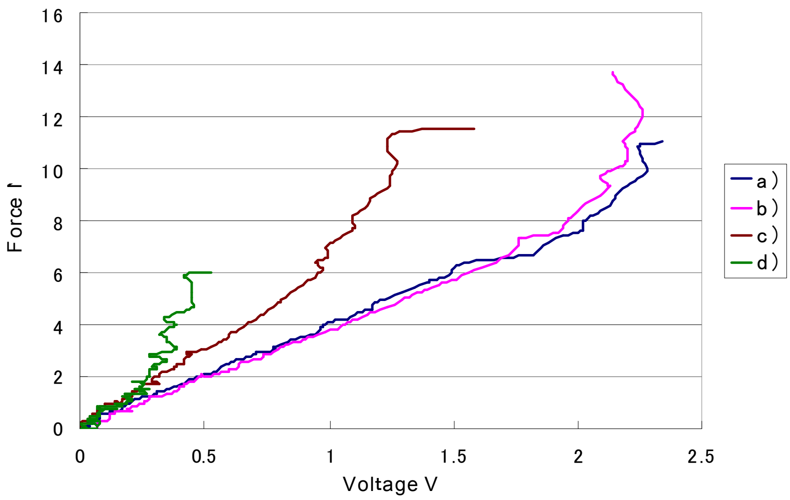


Figure 2.30 Characteristic curve obtained by the FDSS (a, b, c, and d are the different considered cases shown in Fig. 2.29)

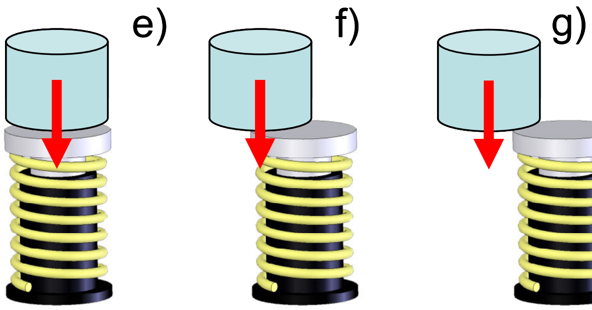


Figure 2.31 Experimental conditions to determine the curve characteristics of the proposed improved FDSS

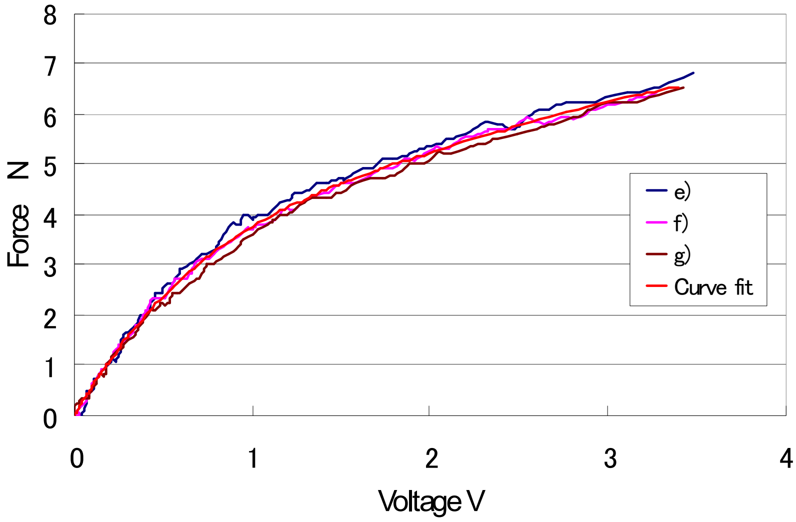
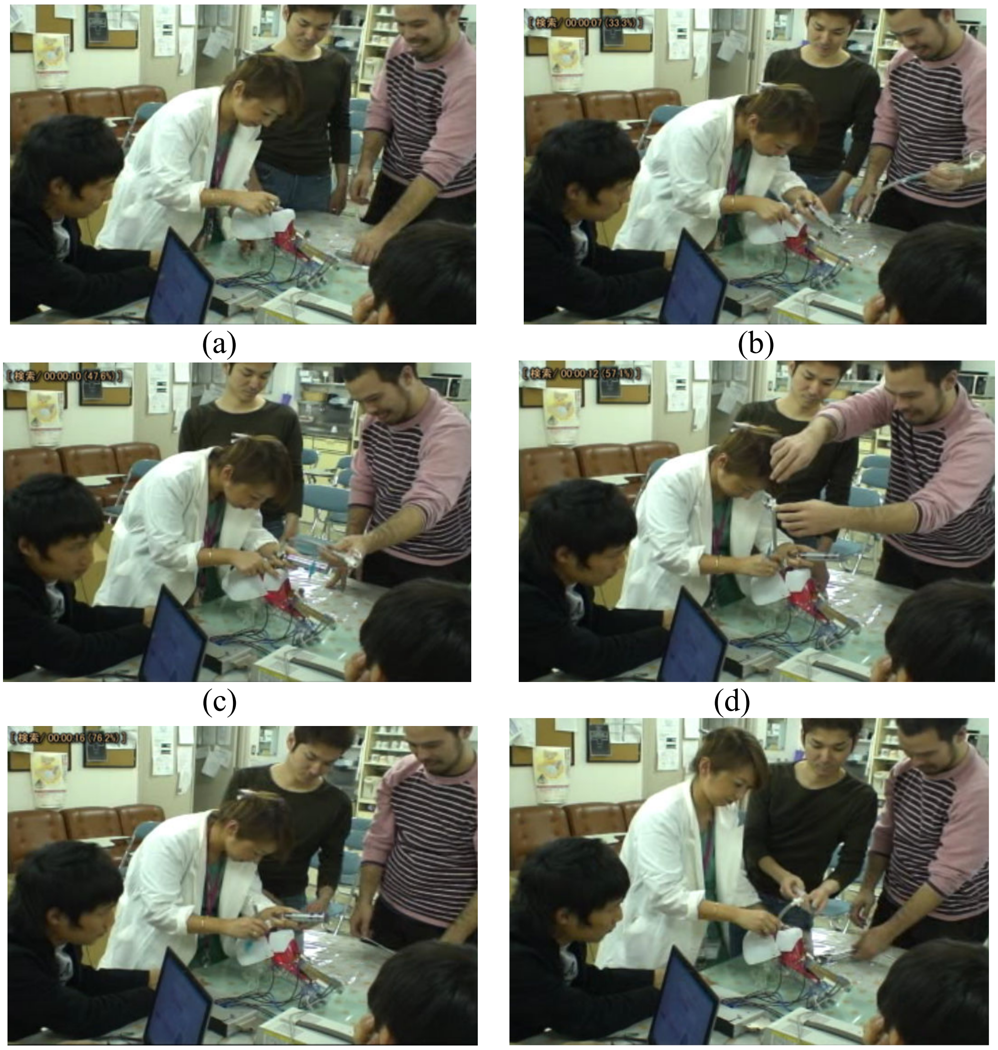


Figure 2.32 Characteristic curve obtained by the improved FDSS

(e, f, and g are the different considered cases shown in Fig. 2.31)

(movement) will be increased, and the characteristic curve of the DDSS can be fit in 2nd order. Using this mechanism, the author can obtain not only output characteristics of the PDSS were obtained again by design an experimental device (Figure 2.24: left).

The author has performed experiments to obtain the characteristic curve of the FDSS with the WKA-1 (Figure 2.30). In particular, the author has designed an experimental device at our laboratory to program the location of the applied forces on the FDSS. The experimental device is composed by a DC-motor, a mechanical link and a load cell attached to the end-effector. Such an experimental device was programmed to applied forces on the FDSS on different locations (Figure 2.29). From the result of the experiment, the characterisitic curves of the FDSS are affected by the applied force along the different axis. From the result of the



(a) (b) (c) (d) (e) (f)

Figure 2.33 Preliminary experiments with doctors:

(a) Setting of the sniffing position and mouth opening, (b) Inserting of laryngoscope into the oral cavity (c) Withdrawal of the laryngoscope (d) Positioning of the endotracheal tube (e) Positioning of the endotracheal tube (f) Inflating endotracheal tube's cuff on the trachea

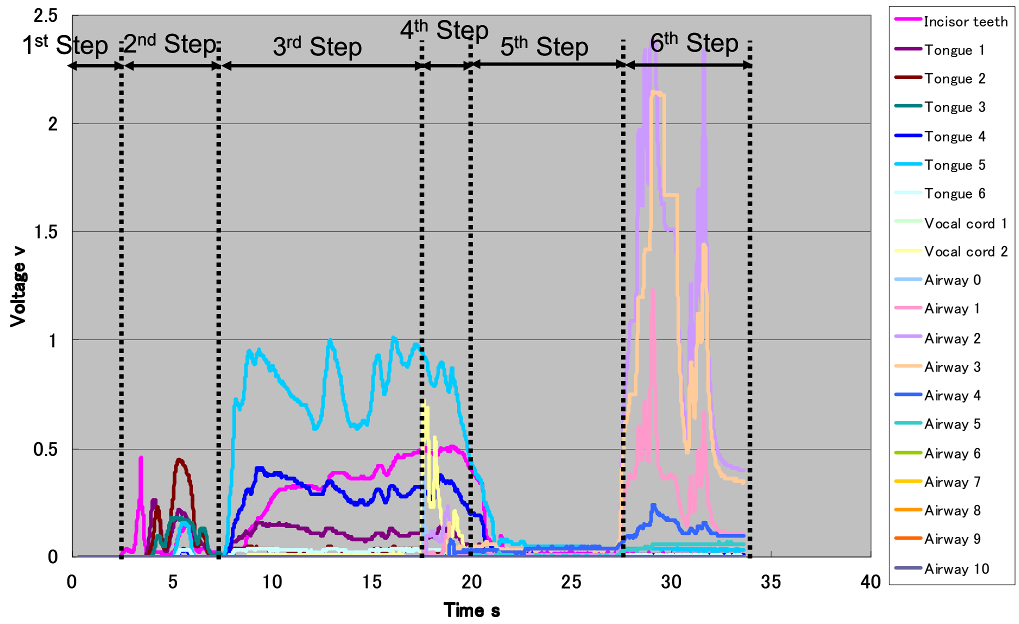
experiment, the author found the FDSS does not have reproducibility. In addition, the author has performed the experiments with the improved FDSS on the WKA-1R. The experimental results are shown in Fig. 2.31. As the author may observe, regardless the location of the applied forces on the FDSS, the characteristi curve of the sensor is the same (Figure 2.32). However, nonlinearlity of the sensor is increased.

B) Verification of the Proposed Sensor Systems and WKA-1R

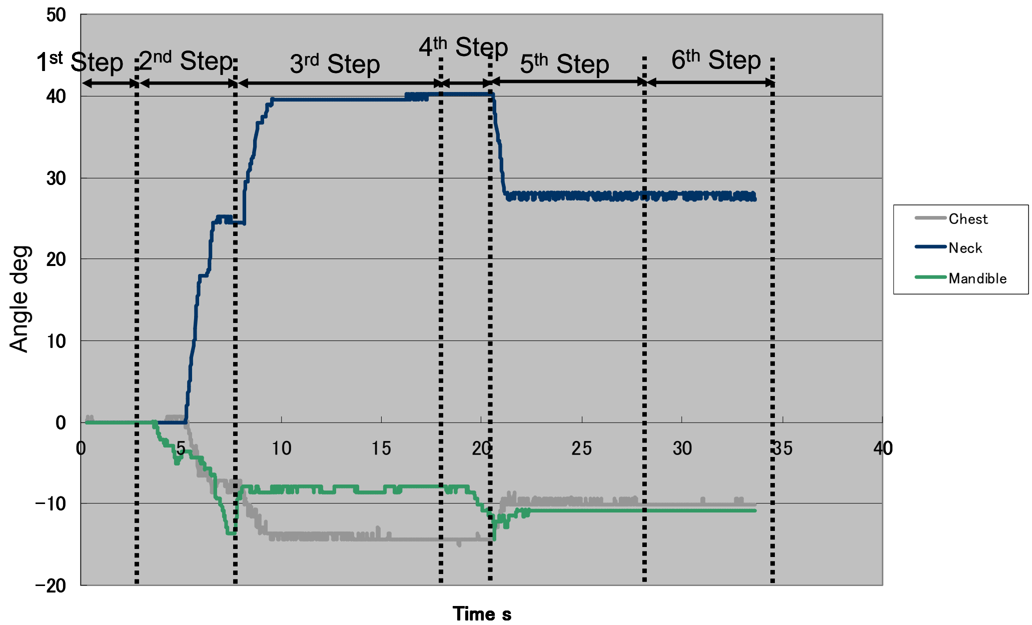
In order to perform preliminary experiments with the WKA-1R, at first, the author has proposed a set of evaluation parameters based from our discussions with doctors and by studying the medical literature [71][72]. The procedure of airway management consists of six main steps (Figure 2.33):

- 1st Step: Setting of the sniffing position and mouth opening
- 2nd Step: Inserting of laryngoscope into the oral cavity
- 3rd Step: Withdrawal of the laryngoscope
- 4th Step: Inserting of endotracheal tube into vocal cord,
- 5th Step: Positioning of the endotracheal tube
- 6th Step: Inflating endotracheal tube's cuff on the trachea

Regarding the measurement of the setting position of the sniffing position and mouth opening (1st Step), the author has attached three potentiometers (Figure 2.14) to obtain the aperture of the mouth, the inclination of the head with respect to the neck and the inclination of lower cervical spine with respect to the chest. Regarding the 2nd and 3rd steps of the airway management procedure, an FDSS was embedded in the incisor teeth to obtain the applied force by the laryngoscope (Figure 2.14). In addition, during the 3rd step, it is important to measure the applied force on the tongue. For that purpose, the author has embedded an array of six FDDS to obtain measure the applied force as well to determine the contact position of the tongue with the laryngoscope blade (Figure 2.14). In the case of 4th step, the author has measured the applied force by the endotracheal tube on the vocal cord. For that purpose, the author has embedded an array of two DDSS on each side of the vocal cord (Figure 2.14). Finally, the 5th and 6th steps are related to the trachea area. In particular, the author has embedded an array of thirteen PDSS and eleven improved FDSS to measure the position of the endotracheal tube's tip while is inserted into the trachea and the applied force due to the inflation of the tube's cuff on the trachea (Figure 2.14). As shown in Fig. 2.34, the quantitative data can be obtained from the WKA-1R, and the author analyzes data segmentation on the each of the procedures of the airway management manually on the data.



(a)



(b)

Figure 2.34 Data segmentation on the each of the procedures of the airway management manually

(a) quatitative information of incisor teeth, tongue, vocal cord, and airway

(b) quatitative information of angle of chest, neck, and mandible

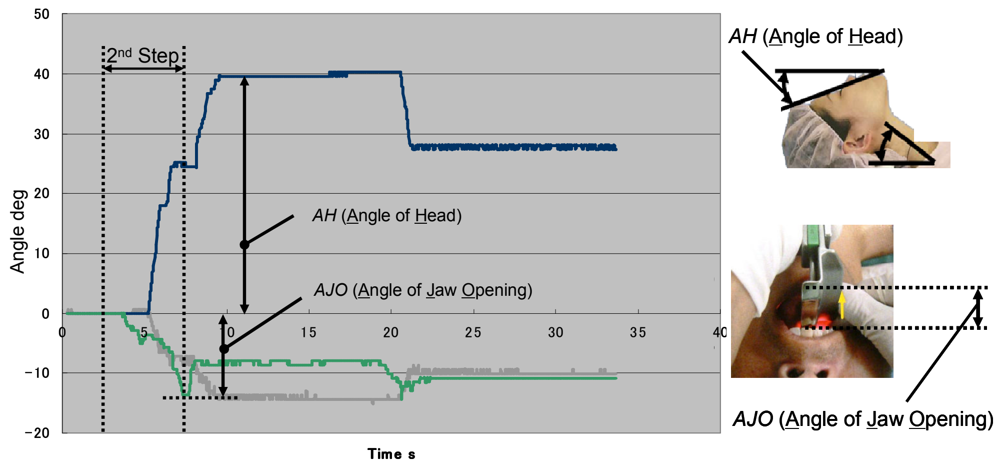
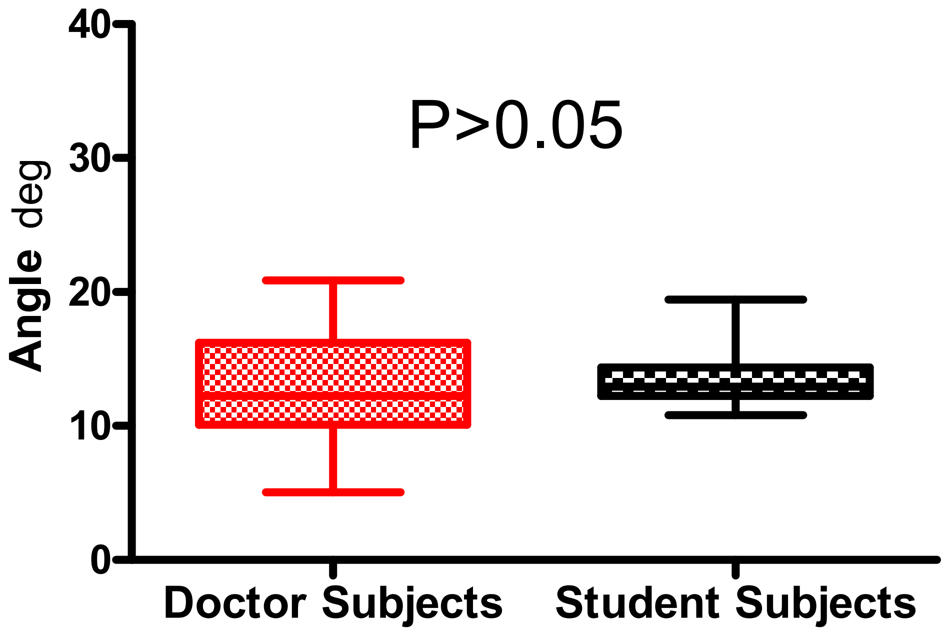


Figure 2.35 Extraction of *AJO* (*Angle of Jaw Opening*) on the procedure step two of the airway management

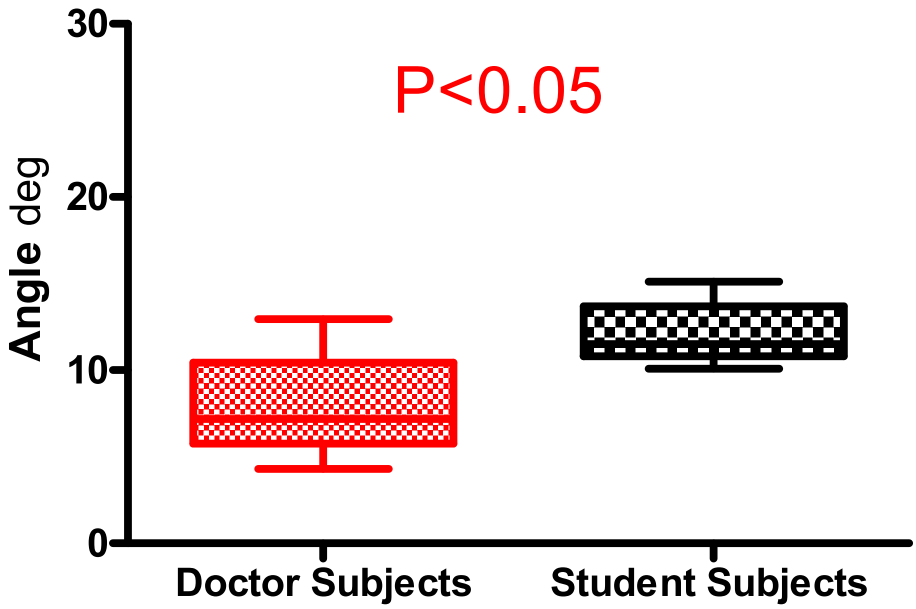
The preliminary experiments were focused on confirming the effectiveness of the proposed evaluation parameters to detect differences among levels of skills. For that reason, the author has collected data from the performance of seven doctors and five unskilled persons. Each of the subjects was asked to repeat the task for three times (Figure 2.33). In the case of the unskilled subjects, the author has demonstrated them how to perform the task by showing videos from experts' performances while performing airway management.

Regarding the experimental results obtained for angle of the *sniffing position* (Figure 2.35), no significant difference was detected between doctors and unskilled subjects (P>0.05) as shown in Fig. 2.36a. This is because the head is constrained to move along a linear guide (Fig. 2.14). In the other hand, while analyzing the angle of the *opening mouth* (Figure 2.35), the author could find significant difference between both groups (P<0.05) as shown in Fig. 2.36b. In fact, the author observed that unskilled subjects tend to excessively opening the mouth. Regarding the *applied force on the incisor teeth*, the author computes the integral of the applied force over the entire time (Figure 2.37). As the author can observe in Figure 2.39a, a significant difference was detected among both groups (P<0.05).

In addition, the author computes the *Intubation Time* (*IT*) and the experimental results are shown in Fig. 2.38 and 2.39b. As it can be observed, unskilled subjects took longer time to perform the tracheal intubation than doctors (P<0.05). In fact, it is well known that tracheal intubation should be completed within 30 seconds in order to provide oxygen into the lung



(a)



(b)

Figure 2.36 Experimental results of evaluation parameters: (a) *Sniffing position*, and (b) a*ngle of the opening mouth*

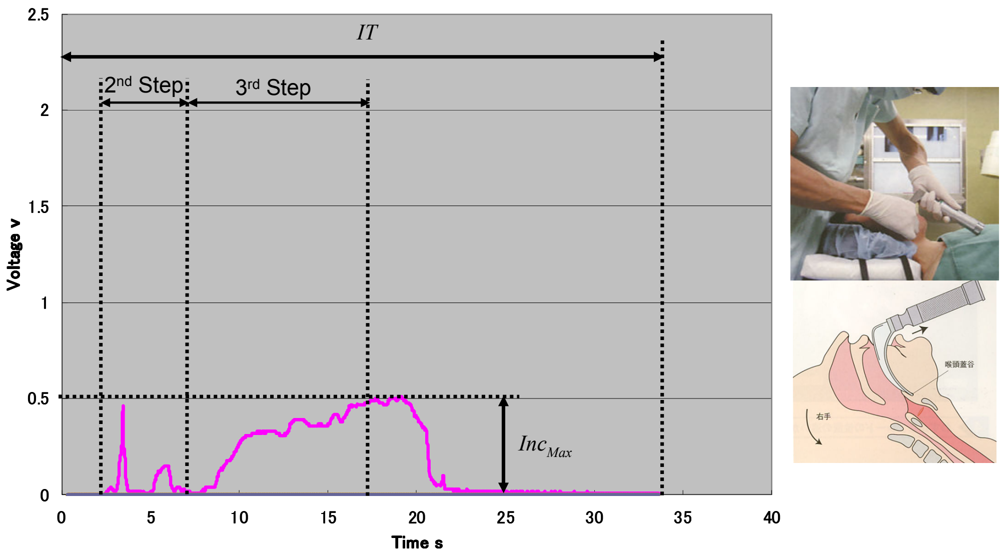


Figure 2.37 Extraction of applied maximum force and applied integral force on the procedure step two and three of the airway management

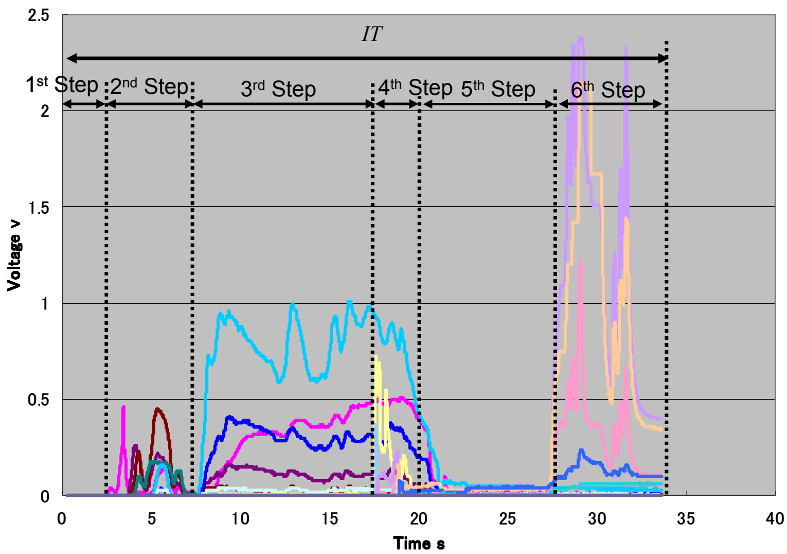
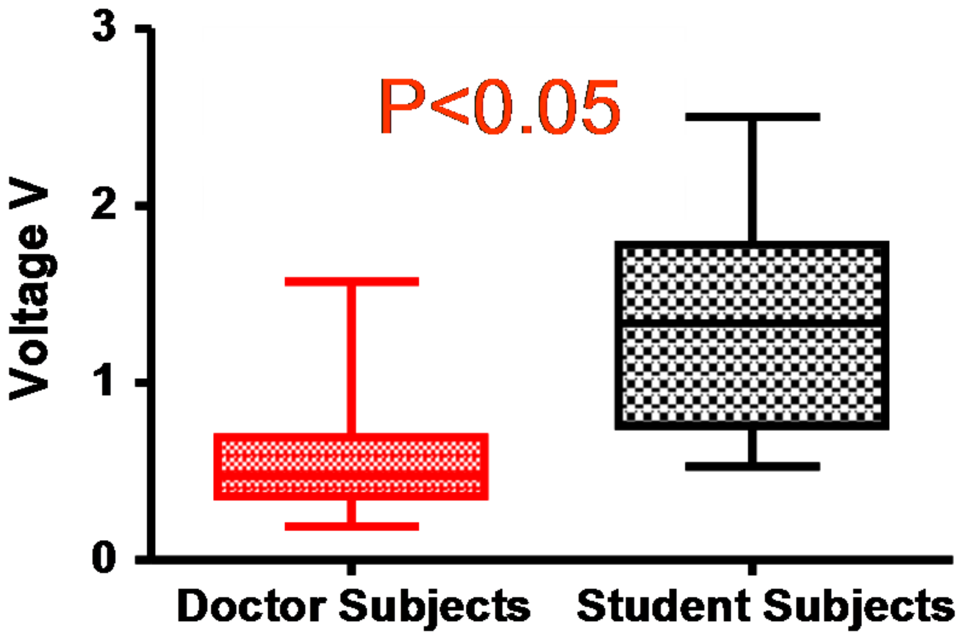
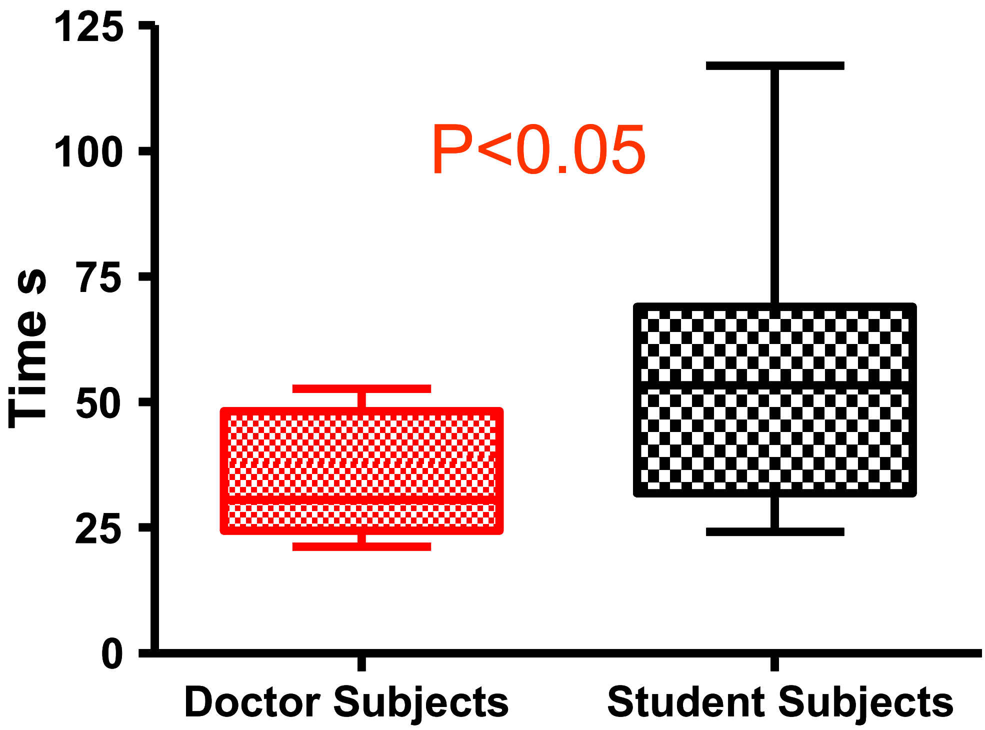


Figure 2.38 Extraction of *IT* (*Intubation Time*) on the total procedure of the airway management

[73][73]. On the other hand, the author analyzed the a*pplied force on the tongue* during the withdrawal of the laryngoscope (Figure 2.40). As the author can observe, the author could find a significant difference on the applied force on the sensor one, the sensor two, the sensor four and the sensor five (Figure 2.41) while comparing both groups ($P<0.05$). Next, the author



(a)



(b)

Figure 2.39 Experimental results of the evaluation parameters: (a) *applied force on the incisor teeth*, and (b) *intubation time*

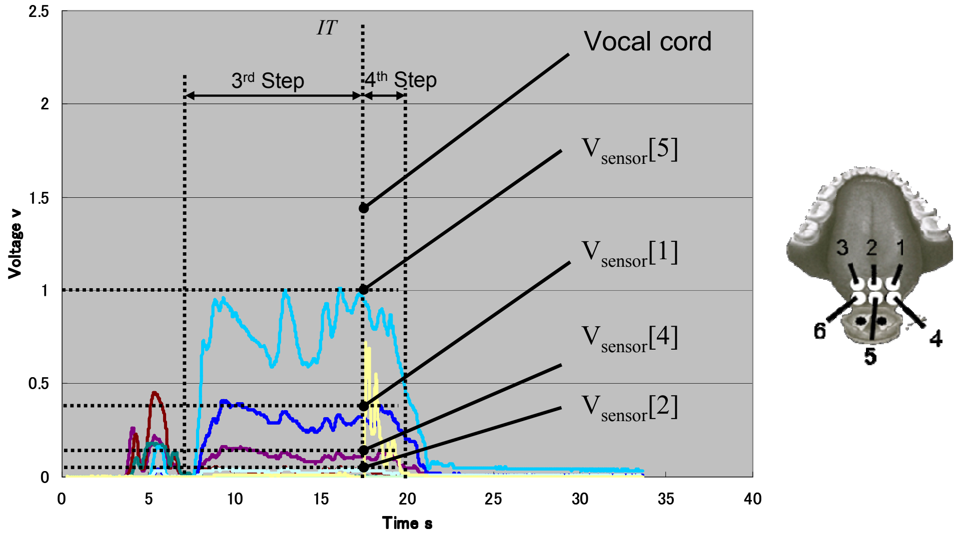


Figure 2.40 Extraction of applied force on the tongue on the procedure step three of the airway management

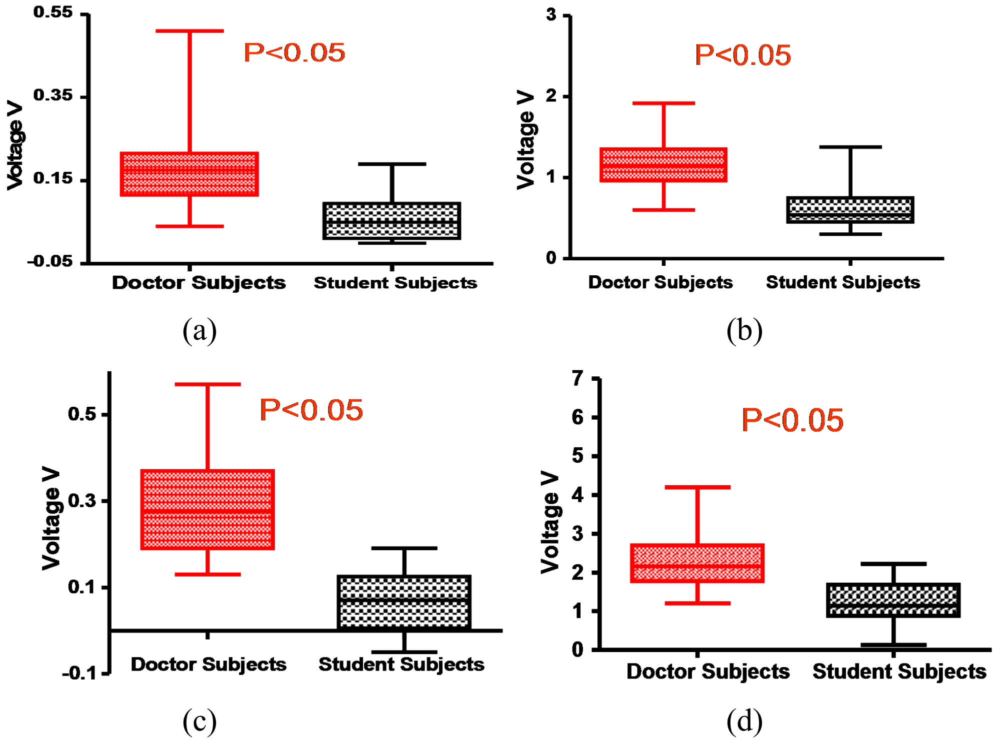


Figure 2.41 Experimental results of the evaluation parameters:

(a) applied force on the tongue No.1

(b) applied force on the tongue No.2

(c) applied force on the tongue No.4

(d) applied force on the tongue No.5

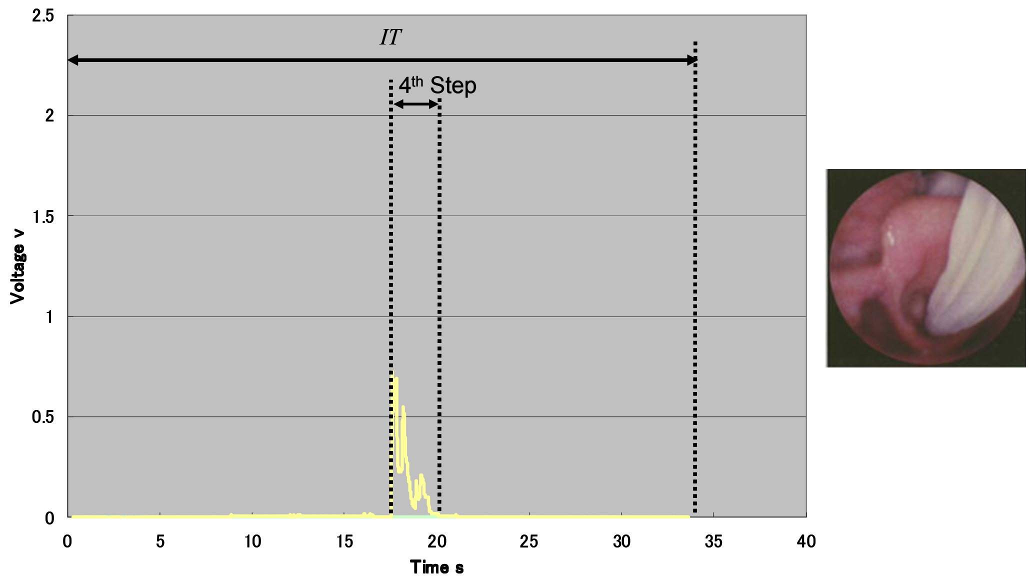


Figure 2.42 Extraction of applied force on the vocal cord on the procedure step four of the airway management

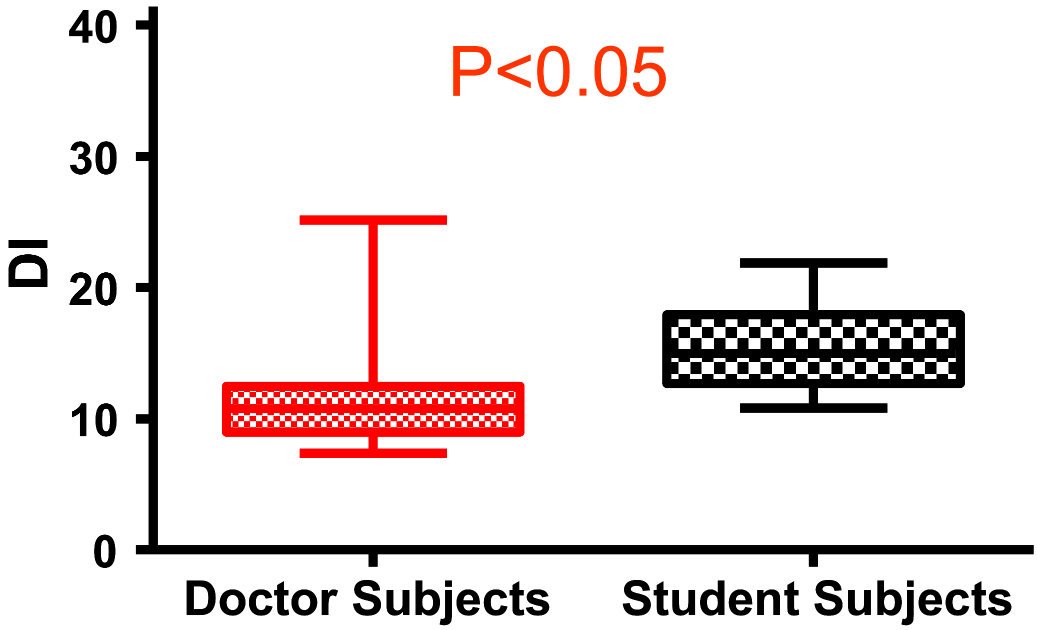


Figure 2.43 Experiment result of the evaluation parameter: *DI* (*Displacement Index*) of the left side of the vocal cord

has analyzed the displacement of the vocal cord caused by the insertion of the endotracheal tube. For this purpose, the author defined the *Displacement Index* (*DI*) which is obtained by calculating the velocity-time integral of tube insertion, as is shown in Eq. 2.13. The velocity (v) is computed by computing the first order derivative of the distance measured from the DDSS and the registred intubation time. As it can be observed in Fig. 2.42 and Fig. 2.43, a

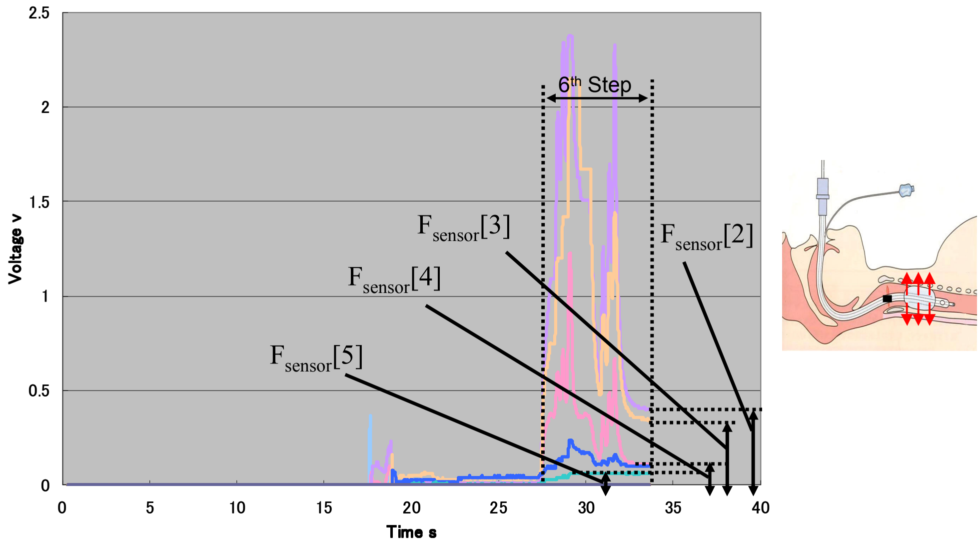


Figure 2.44 Extraction of applied pressure on the trachea on the procedure step six of the airway management

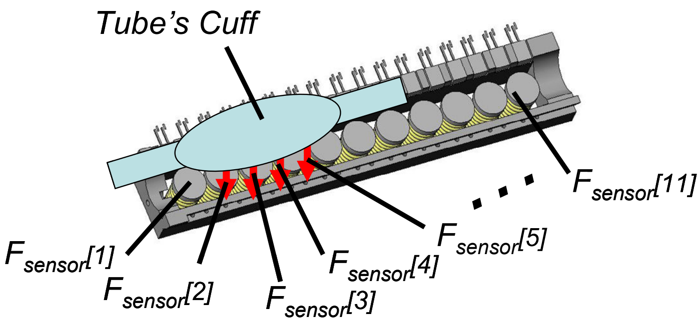


Figure 2.45 Calculation principle of the pressure from the summation of each of the force sensors

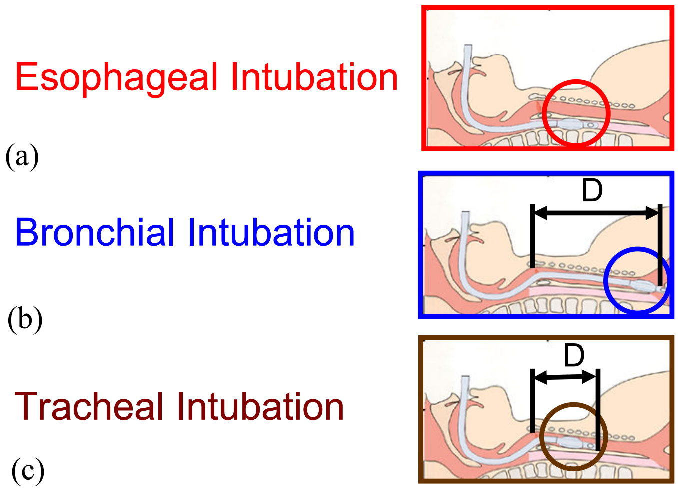
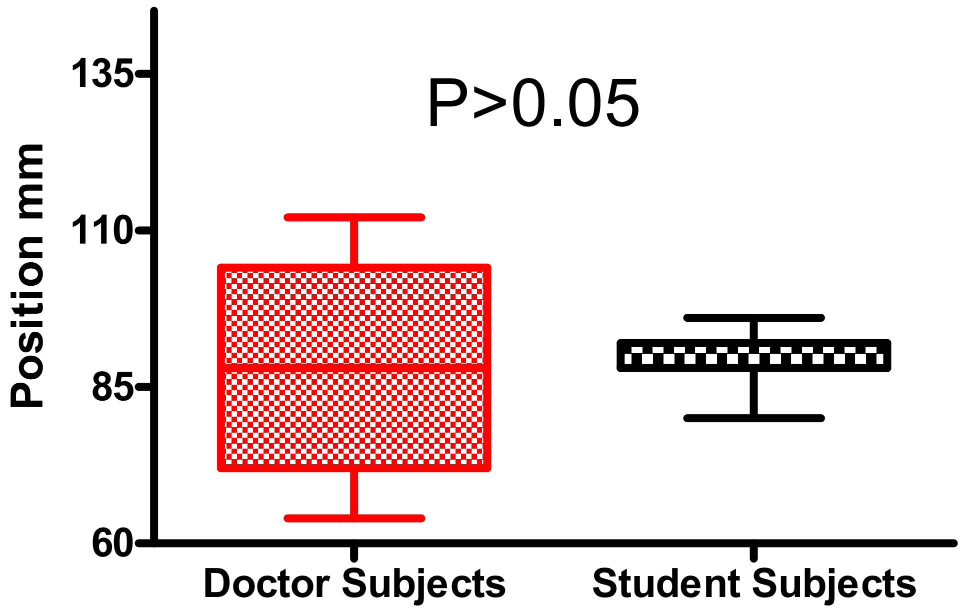
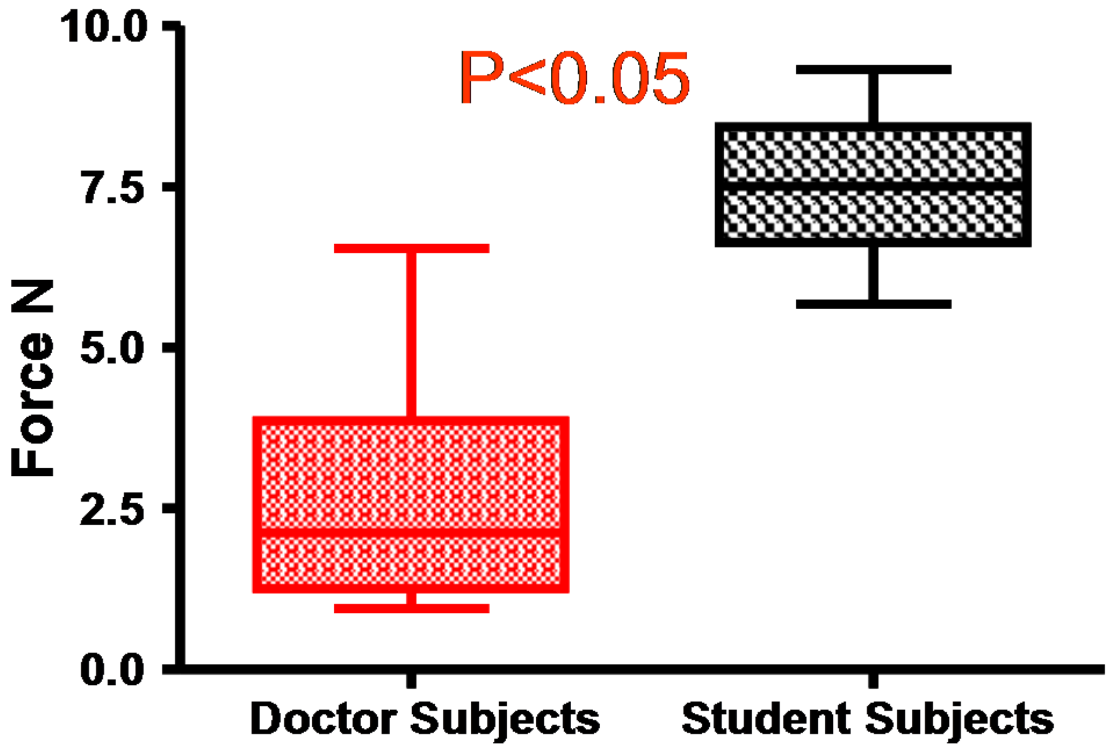


Figure 2.46 Endotracheal tube's position: (a) Esophageal intubation (b) Brochial intubation (c) Tracheal intubation

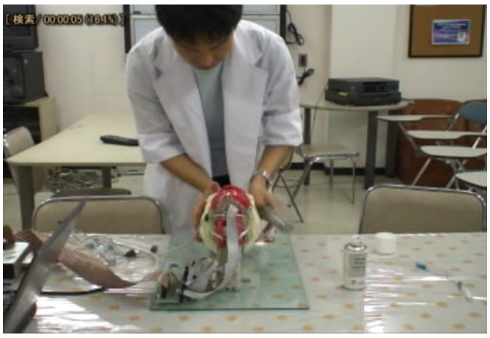


(a)



(b)

Figure 2.47 Experimental results of the evaluation parameters: (a) *endotracheal tube's tip position* (b) applied pressure on the trachea




(a) (b)


(c) (d)


(e) (f)

Figure 2.48 Preliminary experiments with doctors:

(a) Setting of the sniffing position and mouth opening, (b) Inserting of laryngoscope into the oral cavity (c) Withdrawal of the laryngoscope (d) Positioning of the endotracheal tube (e) Positioning of the endotracheal tube (f) Inflating endotracheal tube’s cuff on the trachea

Table 2.2 Result of the calibration between pressure and summation of the forces

Cuff's Pressure	Summation of Force Sensors
$0<P_{cuff}<20$ [cmH_2O]	$0<F_{cuff}<1.8$ [N]
$20<P_{cuff}<30$ [cmH_2O]	$1.8<F_{cuff}<3.0$ [N]
$30<P_{cuff}<40$ [cmH_2O]	$3.0<F_{cuff}<3.7$ [N]
$40<P_{cuff}$ [cmH_2O]	$3.7<F_{cuff}$ [N]

significant difference was detected among both groups while analyzing the left side of the vocal cord ($P<0.05$). Finally, the author has analyzed the position of the endotracheal tube's tip and cuff's pressure parameters. Regarding the endotracheal tube's tip, it is well know that the endotracheal tube should not be intubated into one side of the bronchi (over 120mm from the vocal cord) or into the esophagus, and both groups intubate the tube into the trachea (less than 120mm) (Figure 2.46 and 2.47a).

Regarding the cuff's pressure, the summation of each of the sensors should be converted into the pressure as shown in Fig. 2.44 and 2.45. From the calibration between the summation of each of the sensors' data and the amount of the pressure (Equation 2.14 and 2.15), the applied pressure on the trachea can be calculated as shown in Table 2.2, and the author found the siginificant difference between doctor subjects, and student subjects on the cuff's pressure ($P<0.05$) as shown in Fig. 2.47b.

$$\mathrm{DI} = \int_0^{IT} |\vec{v}| \cdot dt \tag{2.13}$$

$$P_{cuff} \cong k_{PF} \times F_{cuff} \tag{2.14}$$

$$F_{cuff} = \sum_{n=1}^{N} F_{sensor[n]} \qquad [N = 11] \tag{2.15}$$

2.3.2 Verification of the Proposed Evaluation Function to Provide Objective Assessment of the Trainee's Performance while Performing the Airway Management

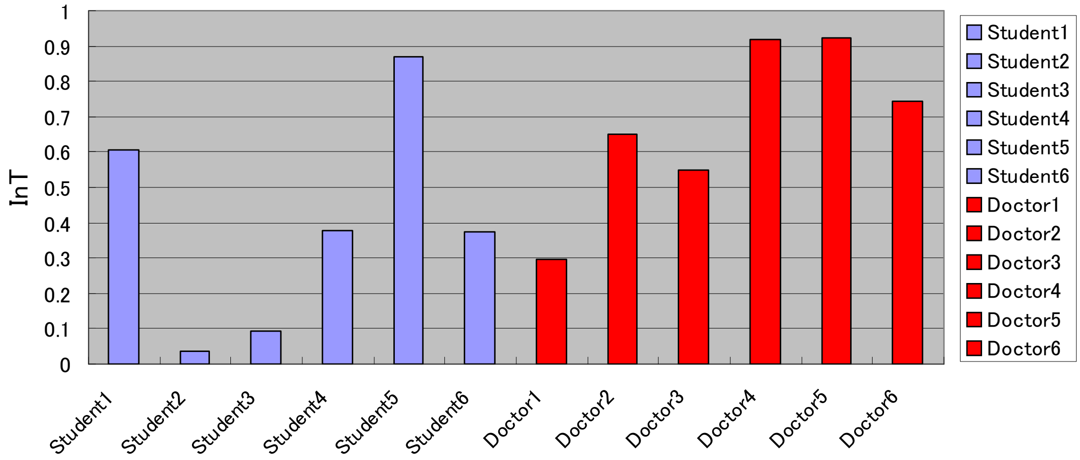


Fig. 2.49 Experimental results of average of each of the unskilled student subjects and doctor subjects on *Intubation Time* (*InT*)

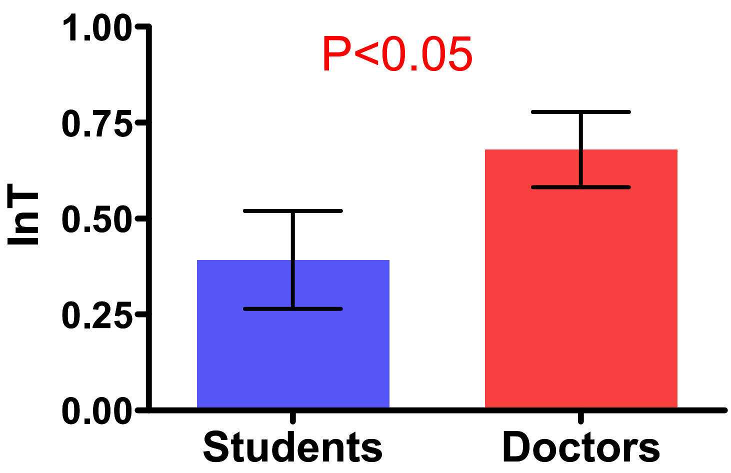


Figure 2.50 Experimental results analyzed using a statistical analysis to determine the differences between unskilled student subjects and doctor subjects on *Intubation Time* (*InT*)

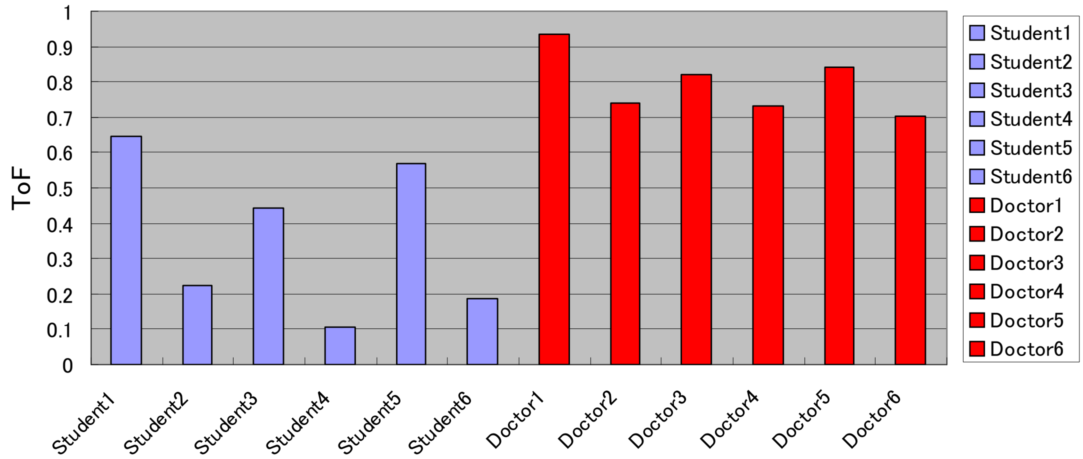


Figure 2.51 Experimental results of average of each of the unskilled student subjects and doctor subjects on *Tongue's Force* (*ToF*)

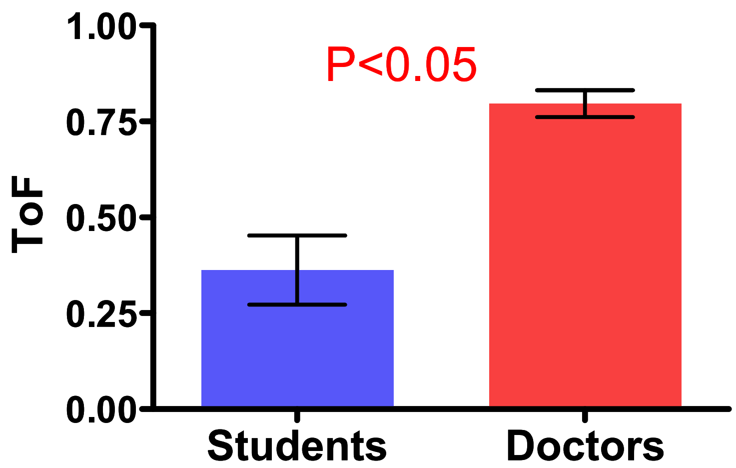


Figure 2.52 Experimental results analyzed using a statistical analysis to determine the differences between unskilled student subjects and doctor subjects on *Tongue's Force* (*ToF*)

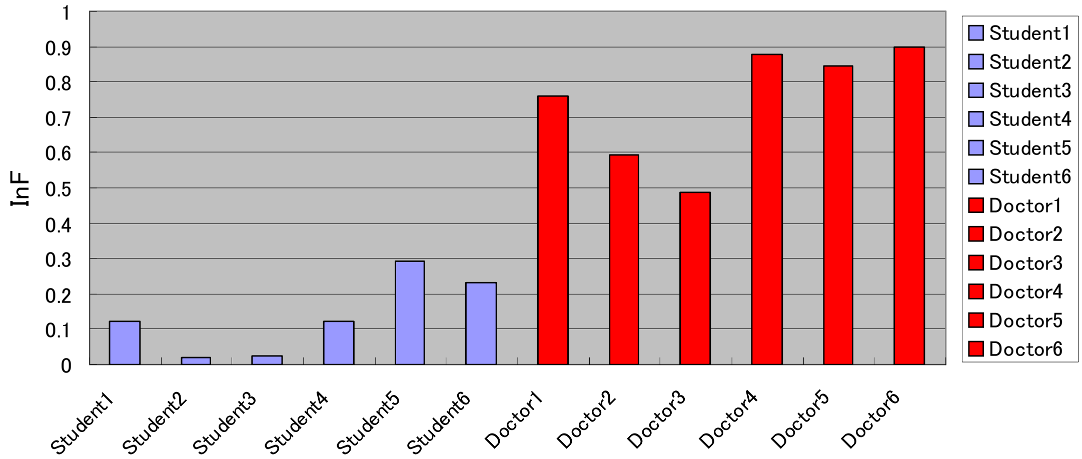


Figure 2.53 Experimental results of average of each of the unskilled student subjects and doctor subjects on *Incisor Teeth's Force* (*InF*)

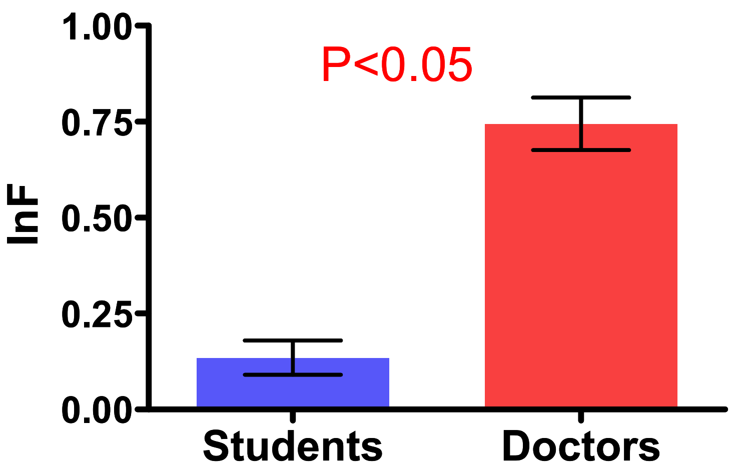


Figure 2.54 Experimental results analyzed using a statistical analysis to determine the differences between unskilled student subjects and doctor subjects on *Incisor Teeth's Force* (*InF*)

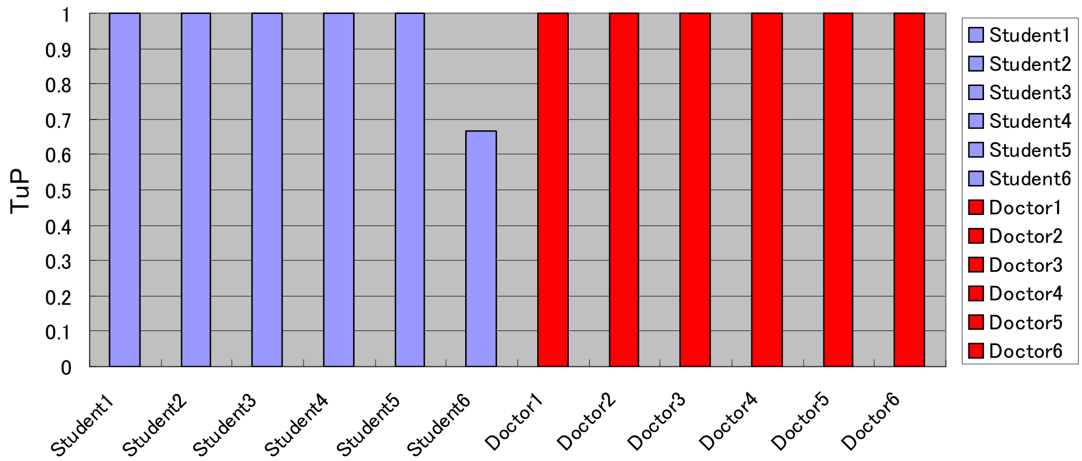


Figure 2.55 Experimental results of average of each of the unskilled student subjects and doctor subjects on *Tube's Position* (*TuP*)

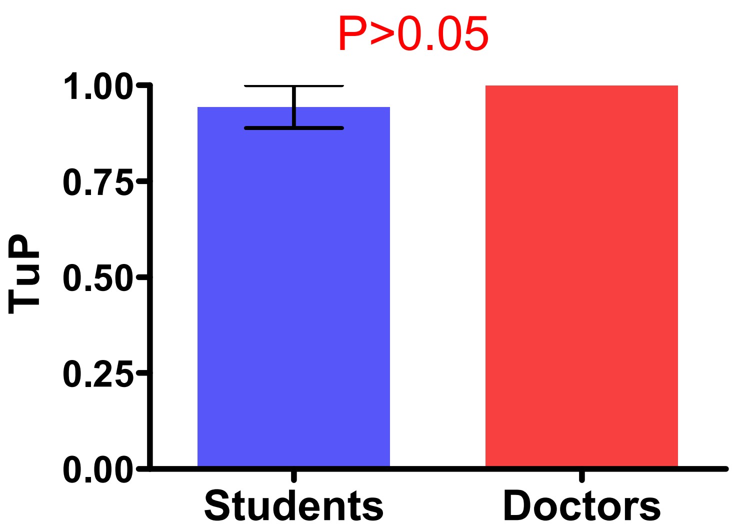


Figure 2.56 Experimental results analyzed using a statistical analysis to determine the differences between unskilled student subjects and doctor subjects on *Tube's Position* (*TuP*)

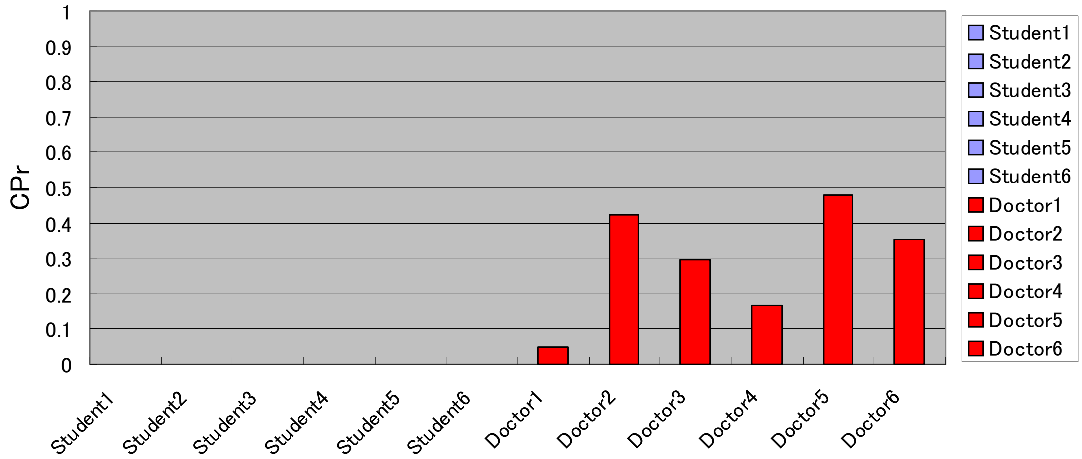


Figure 2.57 Experimental results of average of each of the unskilled student subjects and doctor subjects on Cuff's Pressure (CPr)

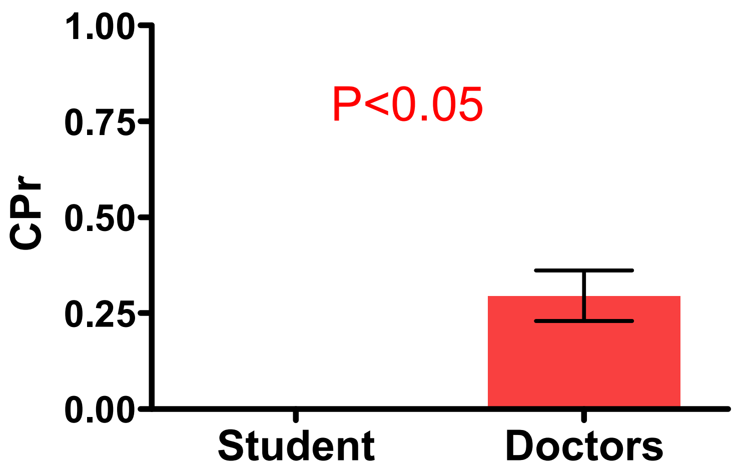


Figure 2.58 Experimental results analyzed using a statistical analysis to determine the differences between unskilled student subjects and doctor subjects on *Cuff's Pressure (CPr)*

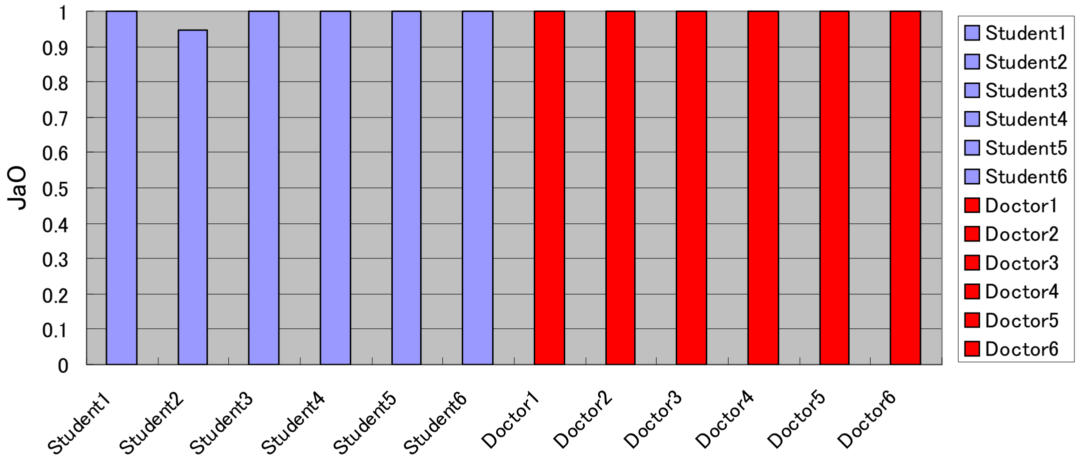


Figure 2.59 Experimental results of average of each of the unskilled student subjects and doctor subjects on *Jaw Opening* (*JaO*)

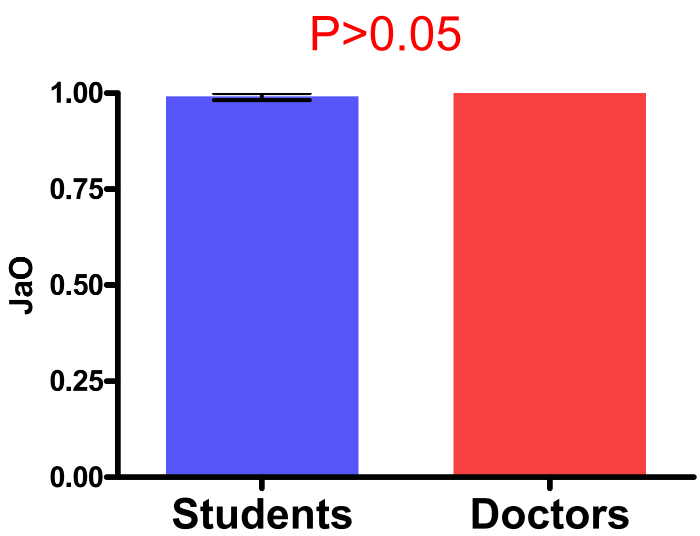


Figure 2.60 Experimental results analyzed using a statistical analysis to determine the differences between unskilled student subjects and doctor subjects on *Jaw Opening* (*JaO*)

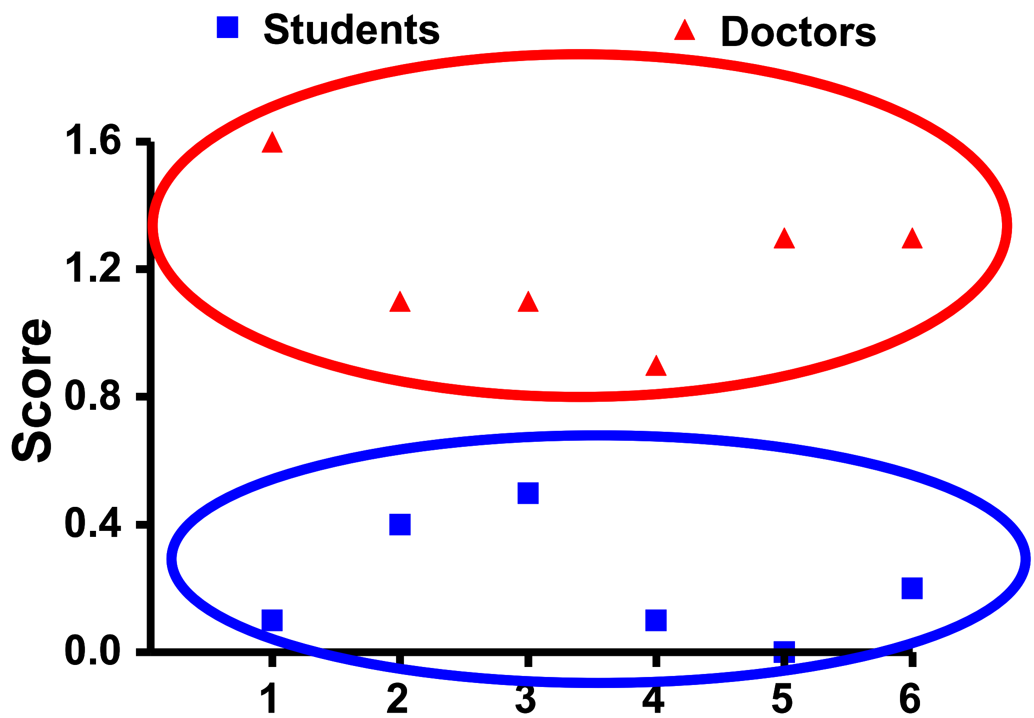


Figure 2.61 Experimental results analyzed using a statistical analysis to determine the differences between unskilled subject group and doctor subjects

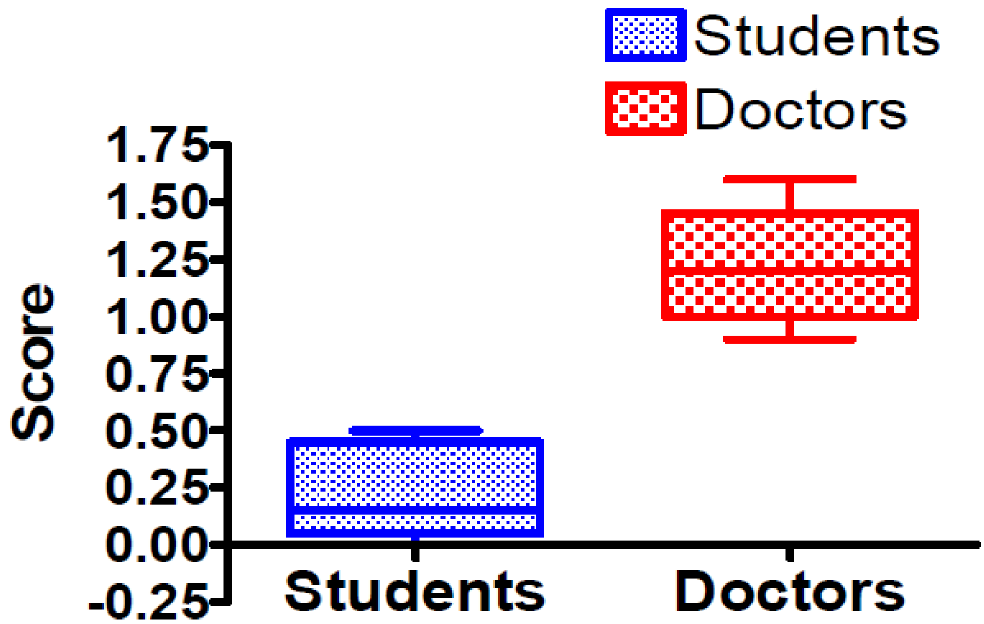


Figure 2.62 Experimental results analyzed using an statistical analysis to determine the differences between average of unskilled subject group and average of doctor subjects

By applying the discriminant analysis, the author obtained the weighting factors as shown in Fig. 2.16. By substituting the obtained weighing factors into the equation 2.1, the evaluation function can be constructed (Figure 2.17).

$$w_{InT} = -1.236, w_{JaO} = 0.093, w_{InF} = 0.631, w_{C\,\mathrm{Pr}} = 0.931, w_{ToF} = 1.333, w_{Tup} = 0.199 \qquad (2.16)$$

$$E_{Airway} = -1.236x_{InT} + 0.093x_{JaO} + 0.631x_{InF} + 0.931x_{C\,\mathrm{Pr}} + 1.333x_{ToF} + 0.199x_{Tup} \qquad (2.17)$$

The author has performed preliminary experiments with the WKA-1R in order to determine the evaluation parameters. In particular, the author have experimentally determined the following evaluation parameters as useful for determining the differences between surgeons and students: angle of the opening mouth, applied integral force on the incisor teeth, intubation time, applied force on the tongue, and displacement index of the left side of the vocal cord. Therefore; in this section, the author has proposed to perform experiments with the WKA-1R to determine the real effectiveness of the proposed evaluation parameters on detecting differences between levels of expertise. In order to confirm the effectiveness of proposed evaluation function, the preliminary experiment was carried out three times with six anesthetists, and six unskilled subjects.

From the obtained data of both of the subjects, the performance index were calucalated by each of the threshold values as shown in Fig. 2.49 to Fig. 2.60. Overall, the performance indexes except the *tube's Position* (*TuP*) have significant differences. Using the experiment data of six anesthetists and six unskilled students, the author applied them to the evaluation function, and acquires each of the doctors', and the students' scores. By applying t-test, the author can found the significant difference on the average score of both of the groups ($P<0.05$) as it is shown in Fig. 2.61 and 2.62. As a result of this fact, the author also found the effectiveness of the proposed evaluation function. As shown in Fig. 2.63, using radar chart, the author shows each of the performance indexes on the radar chart, this radar chart can make the trainee comprehend the trainees' performance of the tasks easily with the score of the evaluation function.

2.4 Discussion

2.4.1 Proposed Sensor Systems and WKA-1R in order to Obtain Quantitative Information of the Trainee's Performance of the Task while Performing the Airway Management

A) Characterisitic Curve of the Proposed Sensor Systems

In case of the sensor's performance, the author found the several problems that the force applied along the different direction or axis affects the characteristic of the FDSS as shown in Fig. 2.29. In constrast, the improved FDSS does not affect the characteristic when the force applied along the different direction or axis on the improved FDSS as shown in Fig. 2.31. However, the improved FDSS is also not consistent relationship between volatage and force according to the position of the applied force on the elastic layer material, and in comparison with the applied force along the center axis, the range of the measured forces are within 0.05%. From the result of these experiments, the FDSS should be implemented into the elastic layer material in order not to affect its characteristic when an amount of the force is applied along the different direction and axis as shown in Fig. 2.65.

For this reason, the FDSS are embedded into the elastic layer material. Form the experiment result, the FDSS could have significant difference on the tongue. Therefore, the author found the possibility to apply them in our system. Near future, the author proposes a set of experiment for the reproductibility of the FDSS. Regardless of the applied force along the different axis, the FDSS has outstanding ability to measure tectile information. In the future, the author consider that the FDSS can be replaced for the tectile sensor or also can be used for the force sensor with the the elastic layer material.

In addition, from the result of the preliminary experiments for the characteristic curves of the FDSS, the improved FDSS, and the DDSS, they are not linear curves, and it can be fit in 2^{nd}, and 4^{th} curve. As shown in Fig. 2.8, the author uses range of linearlity on the photo interrupter from 1[mm] to 3[mm], its characteristic curve has non-linearlity near 1[mm] and 3[mm]. This is why the characteristic curves of the proposed sensor have non-linearity as

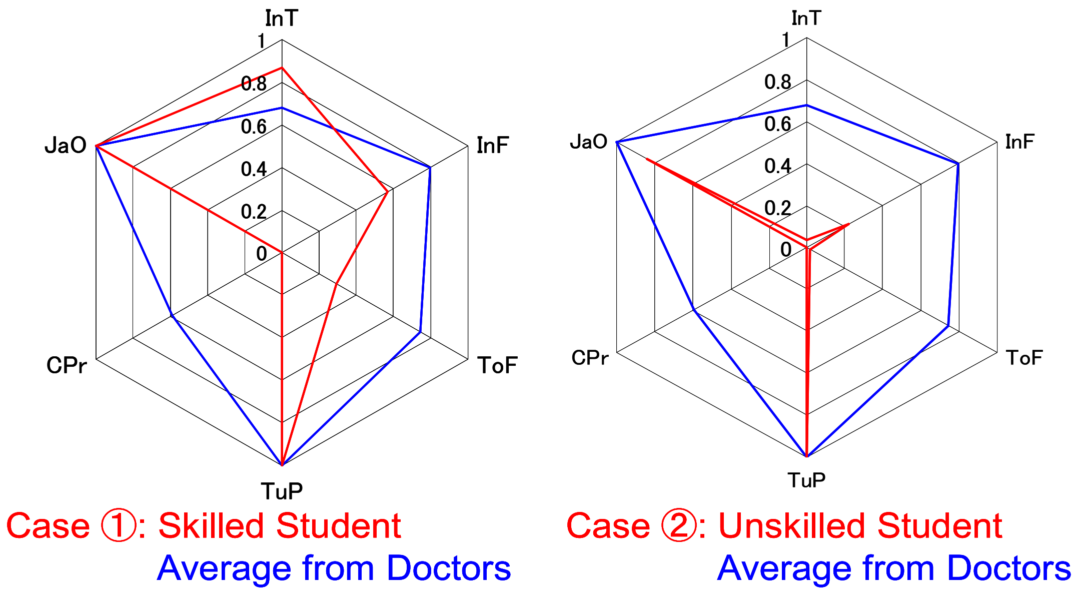


Figure 2.63 Experimental results analyzed using a radar chart

shown in Fig. 2.25 to Fig. 2.27. According to the color of reflective white plastic and distance between the photo interrupter, the characteristic curve of the proposed sensors has diffrernet range of voltage and linearity. Near future, the author also proposes a set of the experiments, and optimizes the colors and the distance for the sensor's linearity.

Moreover, the FDSS and the improved FDSS has also problems. First, for the measurement of the applied force, the sensor should be required for the deformation because without changing the distance between the photo interupter and the white reflective plastic. Second, the FDSS and the improved FDSS can measure only compressive force. For the other applications, the sensor system should be required for the generality and for measuring an amount of the compressive and tensile force. For these reason, in the future, the author should consider redesigning sensor systems in order to compensate the problems of the FDSS and the improved sensor.

B) Verification of the Proposed Sensor Systems and WKA-1R

From the result of the preliminary experiments for the evaluation parameter, the proposed sensor systems such FDSS, improved FDSS, DDSS, PDSS were able to quatitatively detect the difference between the data of the doctor subjects and student subjects,

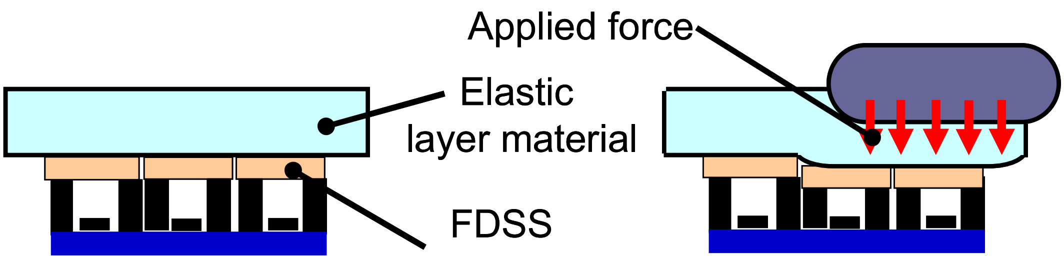


Figure 2.64 Example of good alternative application for the FDSS

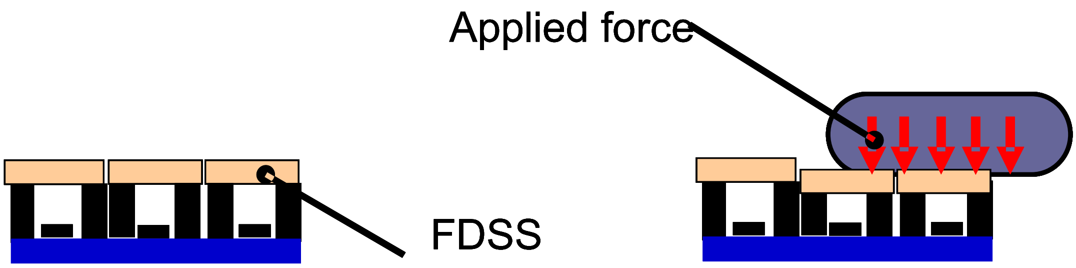


Figure 2.65 Example of bad alternative application for the FDSS

and the author could confirm which sensors are important for the measurement of the trainee's performance of the airway management as shown in Fig. 2.34 to 2.47. From the statical analysis of the obtained data between student subjects and doctor subjects, the author found that the obtained doctors' data have same tendency as the medical literature and the medical textbook are written, but the students' data do not have same tendency as the medical literature and the medical textbook. These are why the statical analsys of both groups has siginicant differences between two subjects. In addition, each of the doctor subjects has different experiences 3 years to 15 years, and student subjects have possibility to have different level of their performance. These also cause both two subjects to have high deviation on each of the results of the data as shown in in Fig. 2.34 to 2.47. However, the obtained data on the tongue sensors should be considered whether they are validate or not. As shown in Fig. 2.41, the obtained data have significant difference between the two groups. However, as the author stated in the chapter 2.4.1, the FDSS has problem, and the obtained data of the FDSS on the tongue could not be verified whether the statical analysises have significant differences or not although the author embedded the proposed FDSS into the thic elastic layer as shown in Fig. 2.65. Near future, the author will propose a set of the experiment for the FDSS with thic elastic layer whether it has reproducibility or not.

2.4.2 Proposed Evaluation Function to Provide Objective Assessment of the Trainee's Performance while Performing the Airway Management

The author also proposed the evaluation function and optimized weighting factors. Although there are many methods such as *Neural Network*, *Genetic Algorithm* (*GA*), *Hidden Markov Model* (*HMM*) to optimize weighting factors. These kinds of the method need a lot of supervisor signals, and the supervisor signal should be consistency not stochastic. For this reason, the author applied discriminent analysis to optimize the weighting factors. From the result of the experiment with doctor subjects, and student subjects, it showed that the WKA-1R was able to quantitatively detect the differences in expertise among participants with a range of skill levels (unskilled trainees, medical students and anesthetists).

Although the proposed evaluation function detects the difference between two subjects, both subjects do not have large score difference. First, the doctor subjects and student subjects, who take part in our experiments to optimize the weighting factors, were too small numbers, and both subjects are various ranges of skills (six doctor subjects have different experiences and six student subjects also have various ranges of skills during the airway management). Second, in order to check the proposed evaluation whether it can be able to quantitatively detect the differences in expertise among participants with a range of skill levels (unskilled trainees, and anesthetists), six doctor subject and six students were joined. However, in this exeperiment, the doctor subjects who had experience for 3 to 14 years were joined. Moreover, each of the students also has various ranges of skills. Those cause the doctor subjects and student subjects to have big standard deviation. Therefore, in order to optimize weighting factors for more exact evaluation function, many doctor subjects who have much experience should be joined, and many student subjects who have low-level skill should be joined. These will make the proposed evaluation function much more correct.

Although the author proposes the *Discriminent Analysis* to optimize the weighting factors, and from the obtained optimization of the weighting factors, the doctor's subjects and the student's subjects were evaluated quantitatively. Since the author focues on the training effectiveness of the trainee's performance, whether their perdormances are improved or not, the author proposed the evaluation function. However, in our case of the airway management, *tube's Position* (*TuP*) can be classified into the three cases such as tracheal intubation, brocheal intubation, and esophageal intubation as shown in Fig 2.46. If the tube is inserted into esophagus and bronchi, the patients are terribly worst situation. At this time, it does not matter whether the score from the evaluation function is higher or lower. Therefore, the author believes that not only the total score but also each of the performance indexes will be an evaluation tool, and the radar chart will provide better understanding on trainee's performance quantitatively.

2.5 Conclusion

In this chapter, the author established a method to provide quantitative information of the trainee's performance of the tasks to trainee while performing airway management, and provide objective assessment. For these reasons, the author proposed several methods, and performed the experiments in order to verify the effectiveness of the proposed methods. The author summalizes this chapter's conclusion as follows:

1. The author considered and proposed sensor systems and WKA-1R in order to obtain quatitative information of the trainee's performance of the task while performing the airway management. For the development of the sensors, the author analyzed the procedure and performance of airway management referring to medical literatures or medical science textbooks, classified each of the steps of the airway management procedures, and defined an amount of the quantity for the trainee's performance during each of the step of the procedures. From the result of the experiment, the WKA-1R which embeds the FDSS, the improved FDSS, the DDSS, and PDSS can detect the difference of the level of the trainee's performance while performing the airway management. From the results of the experiments, Therefore, the author verified the effectiveness of the proposed sensor system and WKA-1R.

2. The author proposed an evaluation function to provide objective assessment of the trainee's performance while performing the airway management. For the evaluation function, a set of threshold values for the normalization were considered referring to the average data of unskilled subject group, anesthetist group, and medical literature. In order to determine weigh coefficients of evaluation function, the author applied discriminant analysis. A set of experiments were carried out to verify the effectiveness of the proposed evaluation function to detect quantitatively differences in levels of skills (doctors and unskilled persons). From the results, the author could found significant differences between the score of anesthetist group and unskilled subject group. From the result of the fact, the author verified the effectiveness of the proposed evaualtion function.

In the chapter two, the author will propose a new sensor system, Tension Compression Detection Sensor System (TCDSS). It is an improved sensor system over the the FDSS and the improved FDSS. The author will present design concept of the TCDSS, and how much the performance is improved compared to the FDSS and the improved FDSS. Although the WKA-1R can measure the quantitiave information of the trainee's performance of the task, this system cannot satisfy the requirements of the innovative training system, and can only fulfill one of the requirements of the innovative training system. In the chapter two, the author will also introduce WKA-2 which can fulfill one of the requirements of the innovative training system. It can reproduce various patient patterns such as airway difficulties, individual differences, and stiffness of the human's muscles.

Chapter 3

Reproduction of Various Patient Patterns

3.1 Purpose: Reproduction of Various Patient Patterns

As shown in Fig. 1.9, the inovative training system should fulfill four requirements: 1) provide useful feedback to trainees and objective assessments of training progress, 2) reproduce the various patient patterns, 3) reproduce *Patient Scenario* for real-world conditions of the task and adjust degree of difficulty for trainee's effective training, and 4) simulate high-fidelity simulated human anatomy as shown in Fig 1.9.

As shown in Fig. 1.9, the innovative training system consists of a high fidelity simulated patient model, sensor system, objective evaluation unit, various patient patterns, and *Patient Scenario Generation*. While the trainee is trained with high fidelity simulated patient model, the sensors of the patient model obtain the quantitiave information of the trainee's performance. The evaluation unit evaluates the trainee's performance from the obtained quantitative information. The evaluation system provides feed back information to the trainee. From this feed back information, the trainee can understand their performances better. In addition, the unit of various patient patterns can simulate the various pattern patients,

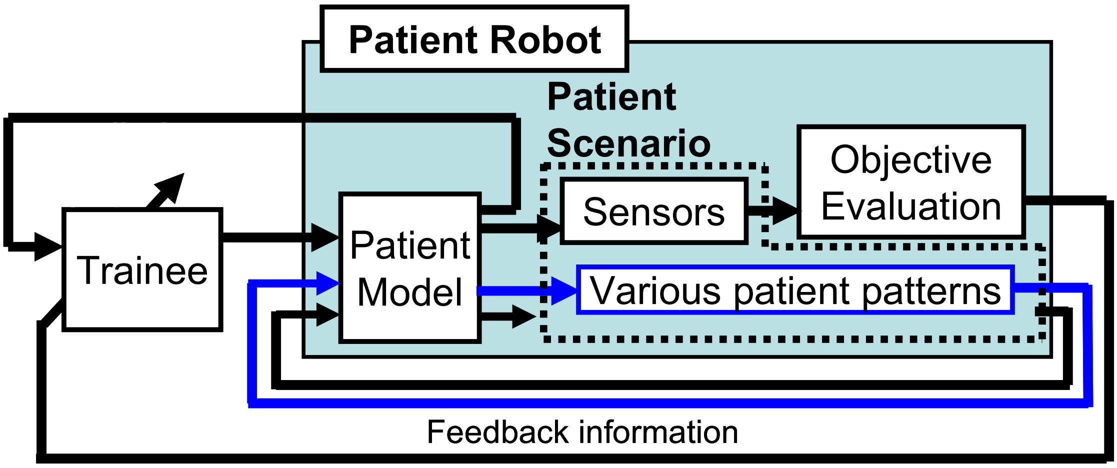


Figure 3.1 Characteristic of Waseda Kyotokagaku Airway No.2 (WKA-2) (bule line is the function of the WKA-2)

and the unit of *Patient Scenario Generation* can simulate real world condition of the real patients which can simulate static or dynamic patient characteristics. At this time, the trainee can cope with the various situations of the patients such as airway difficulties, various individual differences, and this *Patient Scenario Generation* can adjust degree of difficulty for the trainee's effective training. Without the supervisor, the author expects that the trainee can improve their performance of the task.

Therefore, as a first approach of the innovative training system, the author proposed the WKA-1R which can provide quatitative information of the trainee's performance of the tasks, and provide objective assessment. The author verified it through the experiments with doctor subjects and student subjects in the chapter two. Although the WKA-1R has precise sensor systems to obtain quantitiave information of the trainee's tasks, it has problems. First, the FDSS has no reproducibility when the applied force along the different axis on the sensor, the relationsip between the amount of the applied force and output voltage is inconsistent. Second, for the measurement of the applied force, the sensor should be required for the deformation because without changing the distance between the photo interupter and the white reflective plastic. Third, the FDSS and the improved FDSS can measure only compressive force. For the other applications, the sensor system should be required for the generality and the practical application. It should not only be used in our system, but also in other applications. Therefore, the author should consider the new force sensor system for the generality and the practical application.

In order to achieve the concept of the effective innovative training system, as a second step of the innovative training system, the author establishes a way to reproduce the various patient patterns by reproducing various airway difficulties, individual differnences, and stiffness of the human's muslces. As the author has stated in the chapter one, such various patient patterns as the airway difficulties and individual differences in the human anatomy make the airway management difficult. As a result, the medical accidents often occur. Using Robot Technology (RT), the author is trying to reproduce the various pattern patients which can make the trainee trained with the various patients for the effective medical training and copeability (the conventional system can simulate limited patterns of the patients).

In this chapter, the author presents an airway management training system WKA-2 which is designed to reproduce the various patient patterns by embedding actuators and sensors into the patient model. Particularly, the author will present the characteristics of the various patient patterns which are satisfied with human anatomy, and how to reproduce them using the mechanical mechanism, sensors, and control system. Finally, a set of experiments has been carried out whether our proposed training system WKA-2 with the mechanism and the proposed control system verifies the effectiveness or not.

For this WKA-2, the author proposes methods for the devleopement of the training system as follows.

1. Propose sensor systems in order to measure an amount of force information which can measure compression, and tension for the generality. In addition, consider generality and practical application for the proposed sensor system
2. Propose mechanism which can reproduce the various patient patterns such as airway difficulties, and individual differences with the proposed sensors and the actuators. It should be satisfied with human anatomy
3. Propose control system for the reproduction of the airway difficulties and for the simulation of the stiffness of the patient's muscles

A set of the experiments have been carried out in order to verify the effectiveness of the proposed methods.

3.2 Method

3.2.1 Propose Sensor Systems in order to Measure an Amount of Force Information which can Measure Compression, and Tension for the Generality

A) Principle and Design of TCDSS

As the author stated in the section 3.1, the FDSS and the improved FDSS have several problem, and they cannot be attached on each of the wires. In order to solve these problems, the author has designed a Tension/Compression Detection Sensor System (TCDSS). The TCDSS consists of four parts (Figure 3.2): a U-shaped stainless plate, white reflective seal, photo interrupter, and hinge for an applied force. The principle of the TCDSS is almost the same as the improved FDSS and FDSS. In contrast to using an elastic spring or sponge in the improved FDSS and FDSS [35][36][37][38][39], the TCDSS is used in an elastic U-shaped aluminum plate. This U-shaped aluminum plate can be considered as having two symmetrical cantilever beams, as shown in Fig. 3. When an external force such as tension or compression is applied on the point where the distance from the photo interrupter is l_x (Fig. 3.3), the author can obtain the amount of deformation δ_y on the point where the force is applied. Reversely, when the author obtains the deformation amount away from l_x, the author can measure the applied force [82].

The photo interrupter can detect whether an object exits or not. It consists of a

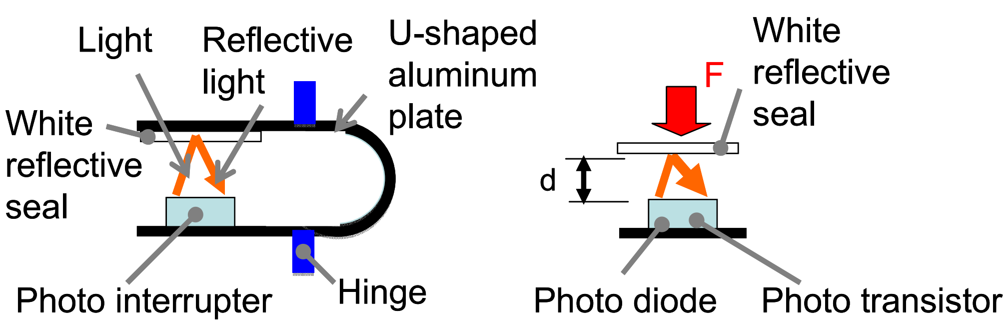


Figure 3.2 Principles of TCDSS

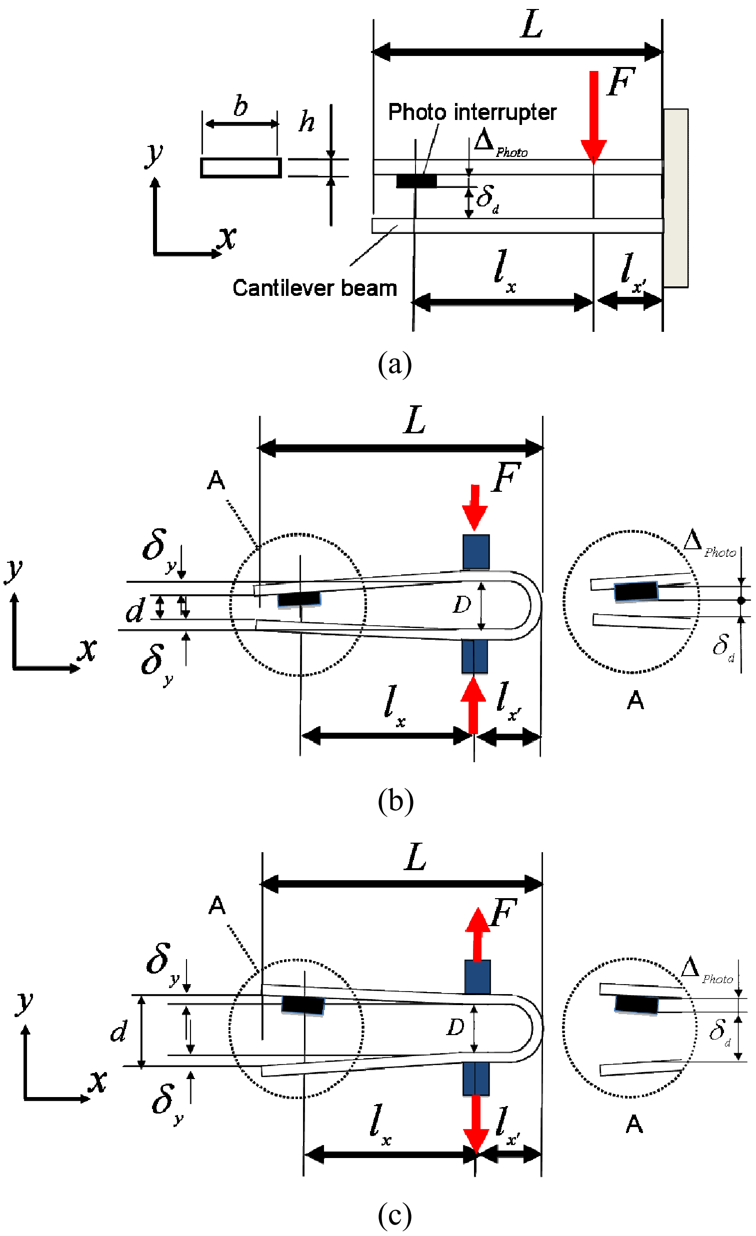


Figure 3.3 Principle of designing the TCDSS

(a) Cantilever beams exerted on applied force

(b) TCDSS exerted on applied compression force

(c) TCDSS exerted on applied tension force

phototransistor and photo diode as shown in Fig. 3.2b. The volume of light is emitted from the photo diode, it is reflected by the white reflective seal, and the volume of the reflective light is absorbed in the phototransistor. As the distance between the white reflective seal and

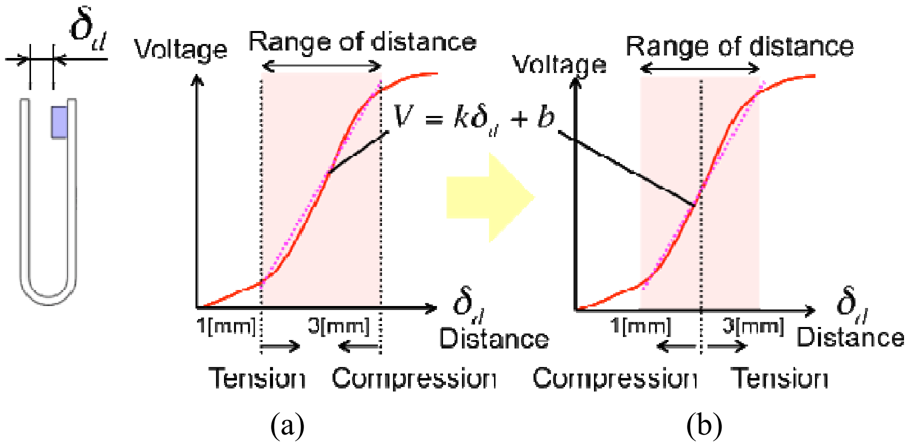


Figure 3.4 Range of photo interrupter

(a) Case of the TCDSS for tension or compression sensor

(b) Case of the TCDSS for tension/compression or torque sensor

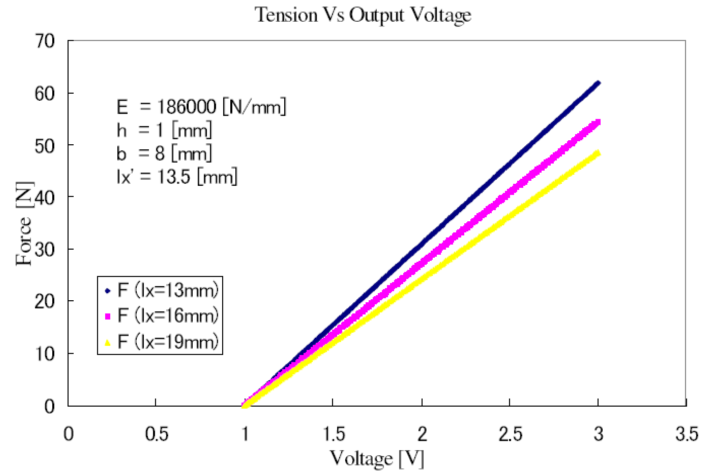
the photo interrupter decreases, the volume of reflective light is increased. Then the current that flows inside of the phototransistor will be increased (Figure 3.2b).

When an external force such as tension or compression is applied on the point where the distance from the photo interrupter is l_x (Figure 3.3), the author can measure the amount of deformation δ_d on the point of the applied force from the output of the photo interrupter, as shown in Eq. 3.1. The characteristic curve between the distance and the output voltage of the photo interrupter has linear characteristics, ranging from 1 [mm] to 3 [mm], and a large amount of current flows at this range, as shown in Fig. 3.4. The author assumes the distance ranging from 1[mm] to 3[mm] as a linear curve, as shown in Eq. 3.1. From these linear characteristics and a large amount of the current of the photo interrupter at that range, the author can measure the distance between the photo interrupter and the white reflective seal on the beam away from l_x as shown in Fig. 3. 3. Using the equations (3.2), (3.3), (3.4), and (3.5) which are derived from the deformation δ_d and of d the cantilever beam, the author can obtain the applied force away from l_x as shown in Eq. (3.6)

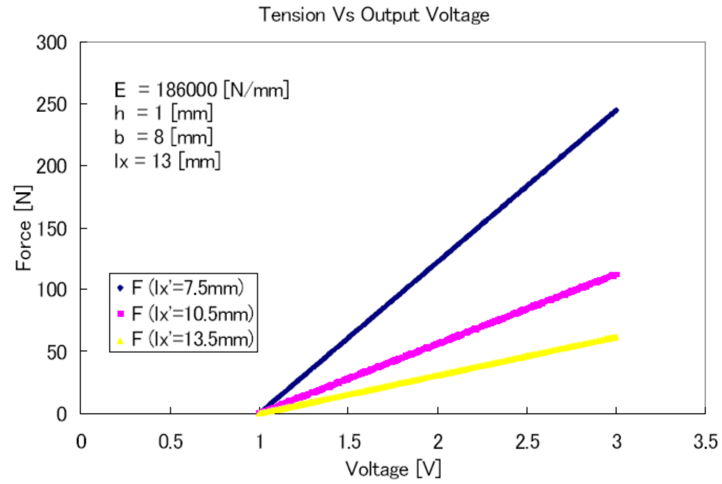
$$V = k\delta_d + b \tag{3.1}$$

$$I = \frac{bh^3}{12} \tag{3.2}$$

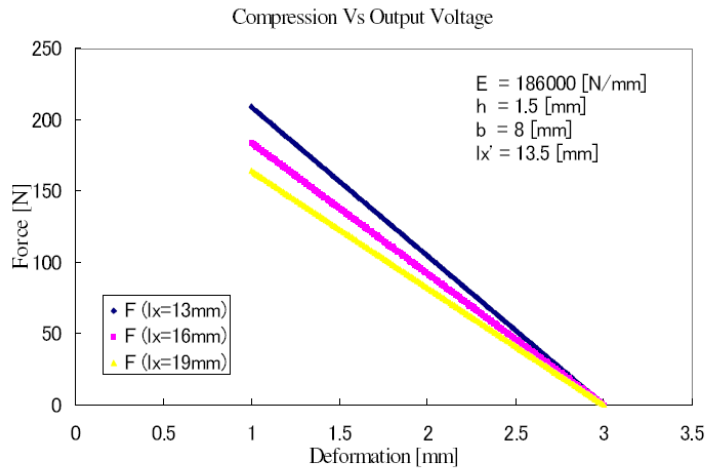
$$\delta_y = \frac{F}{6EI}(l_x{}^3 - 3l_{x'}{}^2 l_x - 2l_{x'}{}^3) \tag{3.3}$$



(a)



(b)



(c)

Figure 3.5 Simulation result of deformation and applied force
(a) Simulation result in case of fixing $l_{x'}$ and changing l_x
(b) Simulation result in case of fixing l_x and changing $l_{x'}$
(c) Simulation result in case of fixing $l_{x'}$ and changing l_x

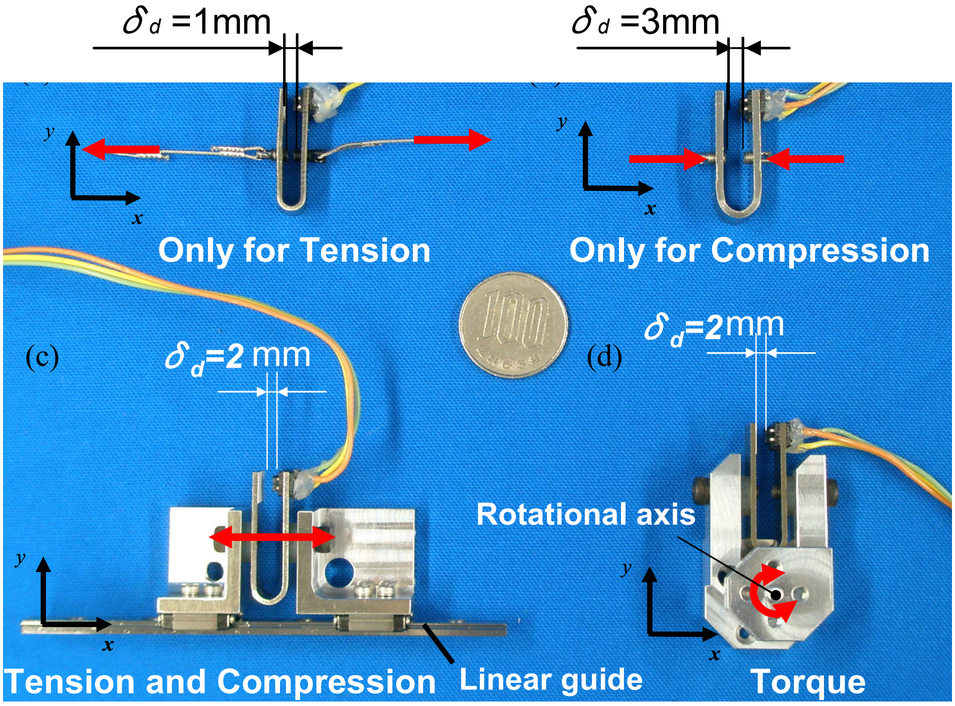


Figure 3.6 Application of TCDSS

(a) Tension (b) Compression

(c) Tension/Compression (d) Torque

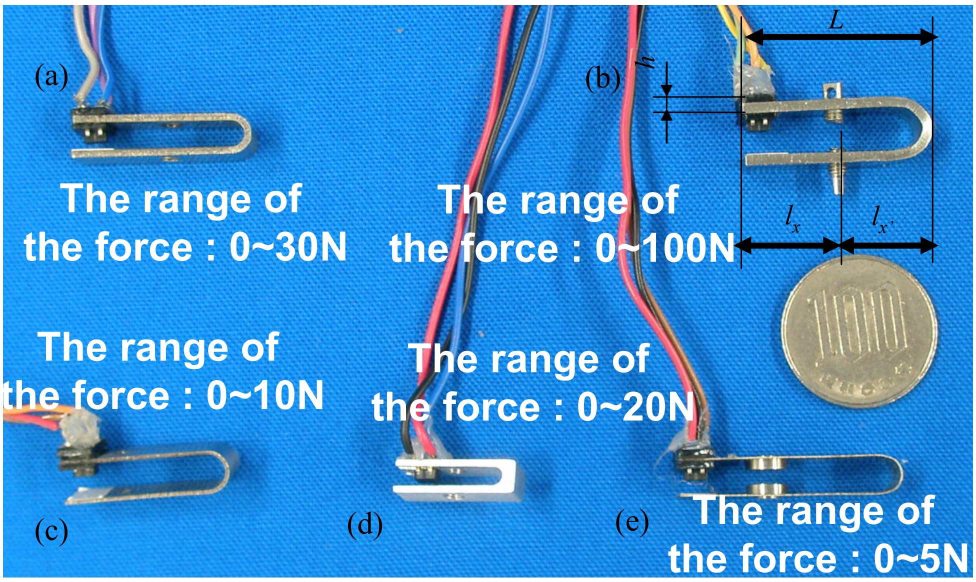


Figure 3.7 Different range of the TCDSS

(a) Range of force : 0~30N (b) Range of force : 0~100N

(c) Range of force : 0~10N (d) Range of force : 0~20N (e) Range of force : 0~5N

$$d = \delta_d + \Delta_{Photo} \tag{3.4}$$

$$d = 2\delta_y + D \tag{3.5}$$

$$F = \frac{3EI \cdot (\delta_d + \Delta_{Photo} - D)}{l_x^{\,3} - 3l_{x'}^{\,2} l_x - 2l_{x'}^{\,3}} \tag{3.6}$$

Moreover, when you choose independent variables such as l_x, $l_{x'}$, thickness of the plate h, and Young's modulus E of the plate as shown in Eq. 3.3, the author can design the force sensor systems which can measure a wide range of force. By combining the independent variable $l_{x'}$, and l_x, when the author fixes the thickness h and width b of the plate and elastic coefficient E (Figure 3.3), the author can obtain a variety of ranges for the force sensor system, as shown in Fig 3.5.

B) Application of TCDSS

The application of this TCDSS can be used to measure only the tension, only the compression, the tension/compression, or the torque (Figure 3.6). According to the application of the TCDSS, the author used different ranges of the distance of the photo interrupter as shown in Fig. 3.6. The application of tension uses the distance, which ranges from 1 [mm] to 3[mm], the application of compression uses the distance ranging from 3 [mm] to 1[mm], and the application of tension/compression uses the distance ranging from 2 [mm] to 3 [mm] for detecting tension and 1 [mm] to 2 [mm] for detecting compression. However, resolution of the ranges of the tension or the compression will be decreased by half as shown in Fig. 3.4.

3.2.2 Propose Mechanism which can Reproduce the Various Patient Patterns such as Airway Difficulties, and Individual Differences with the Proposed Sensors and the Actuators

The design concept of the WKA-2 is as follows: first, the proposed systems should reproduce the physiology and anatomy of the organs involved during the airway management. Second, the WKA-2 should be able of reproducing the various cases of difficult airway, and individual difference of the human anaotomy. Third, an accurate positioning control should be implemented to assure that the tasks conditions are reproduced. Finally, during the airway

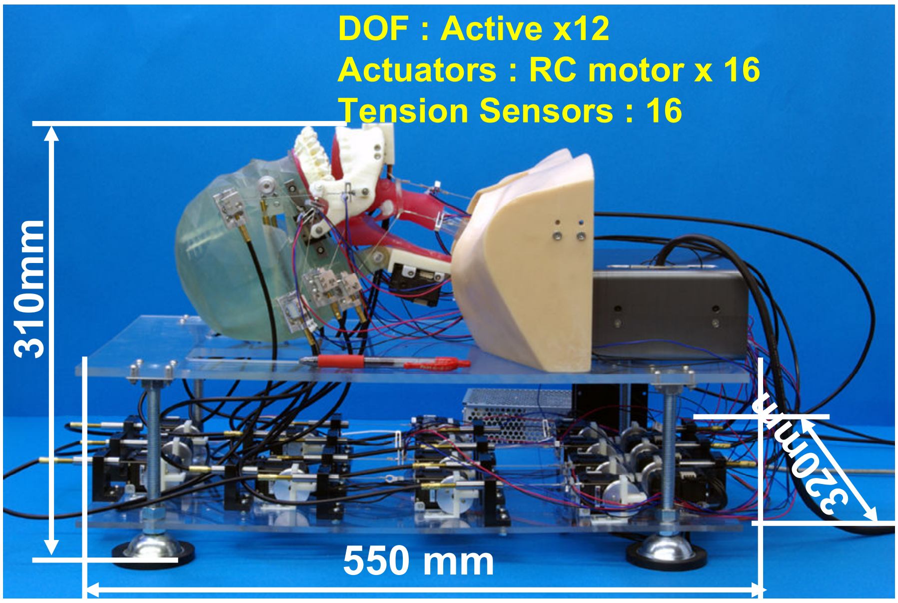


Figure 3.8 Screen shot of the mechanism of the Waseda-Kyotokagaku Airway No.2 (WKA-2): The WKA-2 is designed to embed actuators into a conventional mannequine

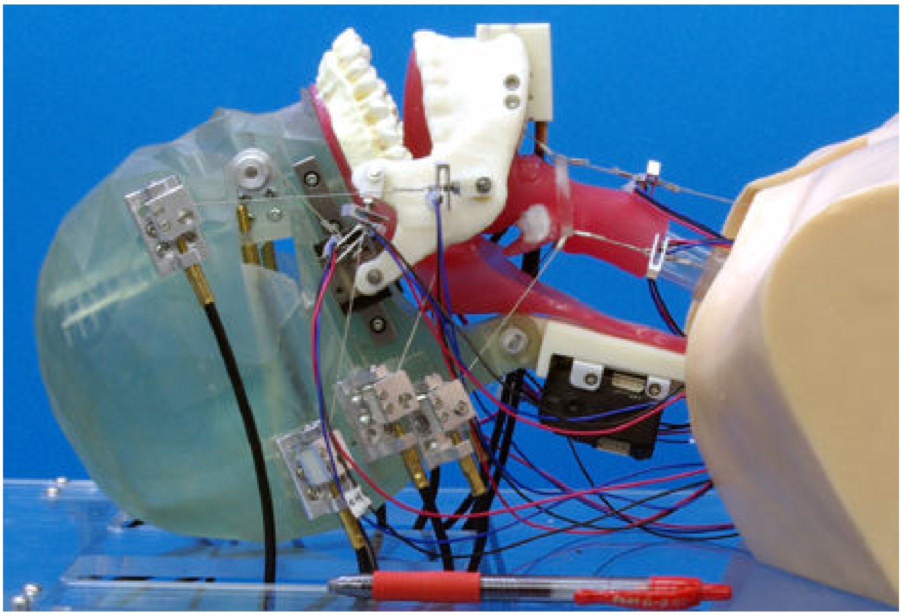


Figure 3.9 Wire driving mechanism of WKA-2: it has been designed to reproduce the various patient patterns