Developments of Operation-field Securing Device and Image Processing Methods for Hemostatic Procedure Analysis in Water Filled Laparo-endoscopic Surgery

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千葉大学審査学位論文

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Chapter 1　Introduction

With the development of medical technology, the medical care provided to patients had various changes. With the development and spread of the medical image diagnostic technology, early detection of lesions has become possible, and the needs for surgical treatment have changed. There is a need for treatment that not only cures the disease but also preserves the patient's quality of life (QoL).

The improving the patient's QoL not only alleviates postoperative pain, but also promotes early discharge and has many advantages such as efficient provision of beds. So, the surgical treatment has been advanced from the conventional open surgery to the proposal of a surgical operation method with a small incision wound and the technical development.

The endoscopic surgery has become widespread and provided the less invasive surgery than the conventional open surgery. In order to further improve the patient's QoL, surgical procedures that do not use the gas, or using the liquid have been proposed to the surgical space. While securing a space with the gas is common, it is a risk factor for adhesion due to desiccation of organs and postoperative complications. In particular, the Water-Filled-

Laparo Endoscopic Surgery (WaFLES), which is an operation method using isotonic solution instead of the gas, reduces damage to normal tissues by maintaining a moist environment in the body cavity during the procedure for organs of the upper abdomen and the retroperitoneal cavity, and reduces an intraoperative burden on the patient. It is expected to contribute to the improvement of the patient's QoL. However, since the endoscopic surgery tends to require the surgeon to have a high level of skill, the burden on the doctor is large. Therefore, there is an effort to reduce the burden on the doctor during surgery by a surgical navigation system that presents information obtained from endoscopic images during surgery and position information of surgical tools to the surgeon and assisting and automating procedures by a surgical robot.

In this study, by providing a stable surgical field environment for the WaFLES technique focused on improving the patient's QoL and developing basic technology for assisting and automating the hemostatic procedure based on the clear visual field using the liquid.

The aim was to provide a safer and more advanced medical environment for patients and doctors than the conventional surgery with the aim of reducing the burden on doctors during surgery.

This paper consists of 5 chapters. First, this chapter described the spread and development of the endoscopic surgery, and it's advantages and disadvantages. In the second chapter, we describe the device development and the ideal WaFLES technique environment for stably providing the WaFLES technique suitable for improving the QoL of patients. In the WaFLES technique environment, a device that can provide a stable endoscopic field of view by the washing effect of the liquid flow, while preventing bubbles from mixing due to rapid the liquid flow and efficiently provide a rectifying environment was needed. We have developed the cistern device that can be installed outside the body cavity and describe the construction of an isotonic perfusion environment that does not contain air bubbles. In the Chapter 3, based on the endoscopic view that enables continuous operative field observation under the stable perfusion environment in the Chapter 2, techniques for assisting and automating hemostatic procedures frequently used in surgery describe the development. In the hemostasis procedure, we focused on the change in the color information of the operative field in endoscopic images of the bleeding from the ablation of organs to hemostasis using protein degeneration by the energy device. Therefore, we describe a machine learning method and a verification experiment to detect the three regions of the organ, bleeding and hemostasis in real-time during surgery. The Chapter 4 describes a method for quantifying the change in the color information that contributes to the end determination of the hemostatic procedure, based on the region detection method constructed in the Chapter 3. Furthermore, by analyzing the hemostatic procedure using the WaFLES environment in animal experiments, we propose an automatic condition for determining the termination of the hemostatic procedure from region detection in this study. Finally, the Chapter 5 describes the conclusion of this study.

1.1 Endoscopic surgery

The endoscopic surgery was introduced in Japan in the early 1990s. It has been widely used as a general surgical treatment option for about 30 years [1]. It has been approved by the national health insurance and has a great track record as a surgical treatment [2].

In the endoscopic surgery, the small Incisions of about 5 to 12 mm are opened in the abdomen and an elongated surgical instrument is inserted to perform the operation [3]. The using forceps instead of a doctor's hand and the endoscopic cameras instead of the doctor's eyes. The endoscope camera [4] can use high-definition images and 4K images [5] using Complementary Metal Oxide Semiconductor (CMOS) image sensors [6] due to the development of sensor technology. Because of this, it is possible to perform surgery with a very clear field of view. Since the incision is small, it greatly contributes to the improvement of the patient's QoL [7-10].

The endoscope is an optical device used for observing the inside of a body cavity without making a large incision in the body, and includes an objective lens, an image guide, an imaging optical system including an image sensor, a light source, and a light guide for transmitting the light [11] (Fig.1.1). It is composed of a display for operative field image display [11]. There are two types of endoscopes used in endoscopic treatment: a flexible endoscope [12] that insertion part can be bent and a rigid endoscope [13] which is made of metal and does not deform. In recent years, a capsule endoscope that encapsulates an objective lens, CMOS-sensor, and light source and wirelessly transmits images [14] has been used for lesion diagnosis. The endoscopic image has a feature that the target region can be magnified and observed as compared with the observation by the conventional open surgery. On the other hand, the depth information is lost [15-17] because the endoscope is the monocular camera. Therefore, it is necessary for the doctor to perform surgery while imagining the three-dimensional structure of the surgical field from the two-dimensional monitor.

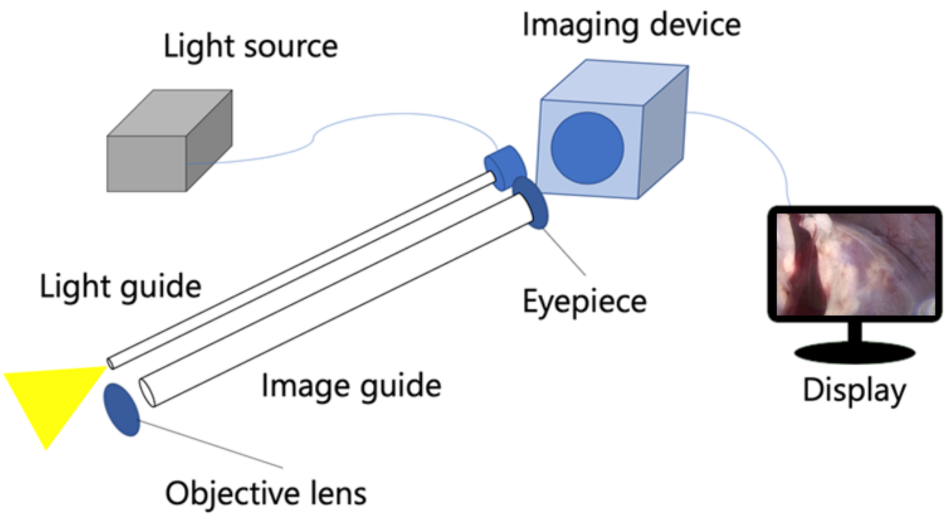

Fig.1.1 The example of the endoscope parts structure.

In the endoscopic surgery, it is necessary to provide a space between the abdominal wall and the internal organs of the abdomen. As this method, there are the pneumoperitoneum method [18] of injecting the carbon dioxide gas into the abdominal cavity and the lifting method [19] of lifting the abdominal wall with a special instrument.

・**The pneumoperitoneumm method [18]**

The pneumoperitoneum is a method of injecting the carbon dioxide gas of 12 mmHg or less into the abdominal cavity to secure a space and perform surgical treatment. It is necessary to use a pneumoperitoneum device that injects the carbon dioxide gas, and a trocar with a check valve function. While the carbon dioxide gas pressure can be expected to suppress bleeding from veins, there is a risk of complications such as the hypercapnia and subcutaneous emphysema because the abdominal organs are exposed to abnormal air pressure for a long time.

・ **The lifting method [19]**

The lifting method includes a full-layer abdominal wall the lifting method in which a device is inserted into the abdominal cavity to lift the abdominal wall, and a subcutaneous steel wire lifting method in which a steel wire is inserted subcutaneously to lift the abdominal wall. The advantages of the lifting method include stability of the operative field, improvement of operability of forceps, diversification of suture ligation, easy removal of excised organs, emergency response during surgery, safety from anesthesia, and economic efficiency.

The advantages and disadvantages of the endoscopic surgery are summarized below [20-22].

Advantages

- Doctors can perform delicate procedures with enlarged images
- It is excellent in the beauty, because the scratches are small and inconspicuous
- The post-operative pain is less than the conventional open surgery, enabling early recovery
- The low risk of wound infection
- The low blood loss

Disadvantages

- Cannot touch organs with hands

・ Surgery time tends to be long

・ Because it takes time and experience to acquire technology, there is a large difference in technology between operators and facilities

・ The surgeon tends to require advanced skills, and the burden on the surgeon is high

The many surgical methods have been proposed that are less invasive than conventional endoscopic surgery, because of the advantages of endoscopic surgery.

1.2 Single Incisional Surgery using the Laparoscope

The conventional endoscopic surgery uses 3 or 4 incisions. The single incisional surgery using the laparoscope is an example of a less invasive surgical procedure than the conventional endoscopic surgery [23-26]. A small incision about 2.5 cm from the navel is used to insert an endoscope and the surgical forceps into the body cavity from one location. There is only one surgical incision, and this incision is hidden in the umbilicus of the umbilicus and is not noticeable after the surgery [27].

The single incisional surgery using the laparoscope requires advanced techniques to perform a surgical operation from a limited small incision, and the surgery may be difficult depending on the medical condition. Therefore, the condition is confirmed by the preoperative CT and ultrasonic examinations, but it is judged whether it is possible for the first time by starting the surgery and observing the state of the organ with an endoscope. If it is difficult, the incisions may be added.

The single incisional surgery using the laparoscope was first indicated for appendectomy in Europe and America in the 1990s. After that, a cholecystectomy was performed, but it was not popular because this surgery was difficult for the surgeon and there was no applicable device. However, The single incisional surgery using the laparoscope started around 2007, because the NOTES (Natural orifice transluminal endoscopic surgery) [28], which is a surgery performed by inserting an endoscope through the stomach or vagina without damaging the body surface, has not reached clinical application. So, the single incisional surgery using the laparoscope was refocused [29].

The Japanese Society of Endoscopic Surgery calls this surgery single incision laparoscopic surgery [27]. Worldwide, in addition to SILS™, it is called Laparoendoscopic Single Site (LESS) Surgery [30], Single Port access (SPA) Surgery [31], Single Port Laparoscopic Surgery (SPLS) [32], Single Site Laparoscopic (SSL) surgery [33], Trans umbilical single port surgery (TUSPS) [34], etc. It is widely used now. The single incisional surgery using the laparoscope is a trademark of Covidien, which sells many surgical instruments for this surgery.

As the example, we describe the practice of a single incision laparoscopic cholecystectomy [27].

1. Access method

Make a 1.5-2.0 cm vertical incision in the umbilicus skin. There are two types of access methods, one using the access port for single incisional surgery using the laparoscope and the other not using it.

a) Multi-channel port method [35]

A laparotomy is performed through a skin incision, and a trocar dedicated to single incisional surgery using the laparoscope is attached.

b) Multiple trocar method [36]

Upon reaching the rectus fascia through a skin incision, the front of the fascia is peeled off there, and a trocar is inserted into the fascia and placed.

The characteristics of the multi-channel port method are that it is easy to set up and there is no leakage of the gas. On the other hand, the cost of the single incisional surgery using the laparoscope 's trocar is high, and the position of the trocar is fixed, making it difficult to operate. The multiple trocar method does not require special equipment and instruments for single incision type and can be performed following the endoscopic procedure. On the other hand, it takes time to insert the trocar, and to leave it, moreover the gas leaks are likely to occur. Thus, there are merits and demerits in the two methods.

2. Making surgical field and the device operation

The procedure by the multi-channel port method using the single incisional surgery using the laparoscope 's port is described. In order to perform the same procedure as the 4-port method used in conventional laparoscopic cholecystectomy, another forceps for an assistant is required. This includes the method of directly puncturing the single incisional surgery using the laparoscope 's port and the method of pulling out the pneumoperitoneum tube and inserting the small diameter trocar through the hole. In general, a method of directly puncturing the small forceps or a gall bladder grasping device under the right intercostal space is performed. It is important to familiarize yourself with the procedure using the dry lab training, etc., because you encounter a situation where your hands and forceps intersect during procedure.

Moreover, when it is difficult to form triangulation with only straight forceps, the difficulty is improved by using bending forceps.

In this way, while surgical procedures that contribute to improving the QoL of patients are developing, it is important to develop dedicated devices and training and support systems that reduce the burden on doctors.

The next section summarizes the problems of minimally invasive surgery procedures.

1.3 Problems in procedures of minimally invasive surgery

As described above, there have been proposed surgical methods that contribute to improving the QoL of patients. Even today, it is required to improve patient's QoL and provide safe surgical treatment compared to the conventional methods. On the other hand, the skills required of the surgeon are becoming more sophisticated than the conventional surgery. Therefore, the burden on the surgeon is increasing. There has been much research and system development to improve this. The surgical navigation system [37-44] based on the medical images is mainly used as a medical procedure support for doctors.

・Surgical navigation system

It is a system that acquires the anatomical information of the patient as the images using the CT (Computed Tomography) [45] or MRI (Magnetic Resonance Imaging) [46] before the surgery and presents the tip position of the surgical tool operated by the doctor on the image in real-time during the surgery. By this, it is possible to confirm the position of the tip of the surgical tool in the anatomy and what the anatomical information around it is, and it supports the doctor's clinical anatomical knowledge. This system requires a system that measures and acquires the position of the surgical tool of the doctor in real-time in addition to the image data of the patient's anatomy information [38]. At the present, the measuring system of the navigation system for tracking the position of surgical tools, which is mainly used clinically, is roughly divided into a measuring method using an optical sensor [47] and a measuring method using a magnetic field sensor [48]. An optical sensor-based measurement system [47] attaches an infrared reflective sphere called a marker to the patient and the surgical tool and acquires the relative positional relationship between the marker and the patient's image data and surgical tool tip position information before starting surgery. Then, the position of the marker attached to the surgical instrument and the patient is recognized by the infrared camera during the operation, and the position of the patient and the distal end position of the surgical instrument are acquired. Similarly, in a measurement system using a magnetic field sensor [48], a marker is attached to the patient and the surgical instrument, and the position information is acquired from the relative relationship between the marker and the image data of the patient and the surgical instrument tip.

However, the method of recognizing the position of the marker is different from the optical measurement system, and the magnetic field generator generates a magnetic field in the surgical operation unit to measure the position of the patient and the sensor coil attached to the surgical instrument.

Based on the using the endoscopic monitor and the navigation monitor side by side, the anatomical information of the patient can be accurately grasped, and the surgery can be performed more safely than the conventional endoscopic surgery. With the introduction of the surgical navigation system, in the terms of accuracy, the boundary line between normal tissue and diseased tissue was clarified, and lesions could be removed accurately. In addition, the improved accuracy made it possible to avoid excessive excision of the normal tissue, which made the procedure more minimally invasive than the conventional surgery [49, 50]. In the terms of safety, it became possible to grasp the position of the surgical instrument and the overall position of the lesion site, which were problems in the endoscopic surgery, which leads to the sense of security and self-confidence of the surgeon himself [51].

Fig. 1.2 The endoscopic surgery using the surgical navigation system

Currently, the surgical navigation systems are used in the otolaryngology and the neurosurgery, etc. The use of the surgical navigation system is limited to some surgery, and it is necessary to develop and study a system adapted to more surgery. Thus, there is an urgent need to develop a surgical environment and procedural assistant device aiming at improving the QoL of patients and reducing the burden on the doctors. Especially, the problem of overtime of doctors is serious now [52]. The purpose of this research is to contribute to the establishment of a suitable surgical environment and the development of surgical assistant technology to solve these complicated problems in the surgery. In the next chapter, we first describe the development of the new medical device aimed at establishing the procedure that is less invasive than conventional endoscopic surgery.

Chapter 2 Development of surgical environment for Water-Filled-Laparo Endoscopic Surgery, WaFFLES

2.1 Introduction

From the viewpoint of maintaining and improving QoL of the patients, the importance and effectiveness of early detection and early treatment of the diseases are widely recognized. In order to maintain QoL, it is important to aim for the early social return by shortening the recovery period after the surgery. Expanding the application of minimally invasive surgery such as the endoscopic surgery, which can effectively preserve the physical function by the surgery with the less incision of the muscle layer, greatly enhance the benefits to the patients. Fewer surgical incisions not only reduce postoperative pain but have fewer complications such as organ adhesions and intestinal obstructions than conventional open surgery [53].

On the other hand, compared to the conventional open surgery in which the doctor can grasp the condition of the surgical field and perform a procedure

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Published patent on this chapter
[69] Matsunaga Y, Ishii T, Igarashi T, Operation field-securing device,
Patent number: 10314569(USPTO), 06/2019.

using his or her own eyes and hands, the abdominal wall is sandwiched and the depth of operation is limited because of using the surgical instrument and the monocular camera with limited freedom of the operation. Since it is a two-dimensional image that is hard to grasp, and the sense of the camera and the procedure change due to the rotation of the camera, the endoscopic surgery requires medical personnel to acquire many advanced techniques. However, due to the efforts of doctors and advances in many assistive technologies, the range of the applicable diseases is steadily expanding. For example, a virtual reality system [54] is used to the practice system that allows the trocar to be installed while preventing damage to the organs and the forceps.

The study and innovations in the engineering technology are essential elements in the development of the medical treatment to date. For example, the doctor's eye during the endoscopic surgery changes from a cylinder that only sends light into the body to a rigid scope or a flexible scope, which reduces the burden on the patient. The merits of observing an object through an endoscope are increasing as the image quality and functionality become higher and higher. In addition, the surgical instruments used in the endoscopic surgery make full use of various energies such as the electricity, the ultrasound, and the laser to enable more accurate and safe procedures compared to the conventional procedures.

Conventionally, in the laparoscopic surgery that was performed at multiple incisions, a method called the single incision method for inserting all surgical tools from a incision is performed. Currently, robot-controlled surgical tools are being used [55-57]. There are the new surgical techniques or the technological advances, such as the technology that enables more precise surgical operations by remote control and development reports of ultra-small diameter surgical instruments called needle surgery for performing surgery with extremely the small incisions [58,59].

In order to perform the endoscopic surgery in a narrow body cavity, it is necessary to construct the enough surgical space to secure the focal length and field of view of the endoscope and the operating space for the surgical instruments and expand the abdominal cavity with carbon dioxide pressure. This space is secured by the pneumoperitoneum method or the lifting method in which the abdominal wall is pulled by a device.

On the other hand, as a new surgical space securing method, the WaFLES technique [60], which is a surgical procedure in which the body cavity is filled with the liquid called isotonic fluid that is close to the osmotic pressure of the human body instead of pneumoperitoneum, and surgery is performed in the fluid has been proposed. In this chapter, we developed the device based on the WaFLES technique. Therefore, in the next section, the benefits and features of this surgical technique are described.

2.2 The benefits and features of WaFLES

In the WaFLES technique [60], the ascites state is artificially created by filling the surgical space with a fluid called isotonic fluid, which is close to the osmotic pressure of the body fluid, instead of pneumoperitoneum that was conventionally performed with the carbon dioxide gas (Fig.2.1).

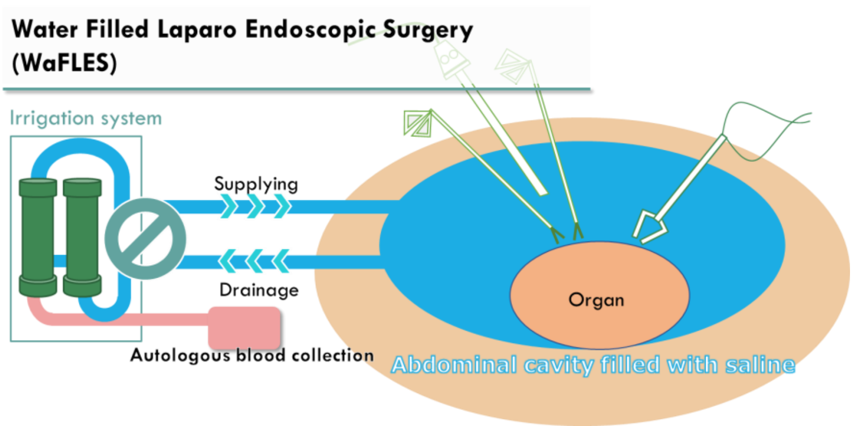

Fig.2.1 The WaFLES system overview.

The devices that is almost the same as the conventional endoscopic surgery can be used, and when washing the blood in the various surgery [61], a method is used in which the blood is washed away using an isotonic solution as a perfusate and suctioned. Therefore, there is no big change in the surgical method. For the liquid, a method is used in which the liquid is aspirated from the body by the perfusion device, the excised pieces and the blood components are separated in the machine, and then reperfusion is performed. The purpose is to perform surgery with the clean surgical field while continuously purifying the liquid. In the conventional endoscopic surgery, an isotonic solution is used to wash the inside of the body to remove the residual blood by washing the inside of the body and aspirating the body. Also, by using the liquid with the temperature close to the body temperature, the hypothermia is prevented [60].

During the conventional endoscopic surgery, the abdominal wall is lowered by its own weight, which narrows the surgical space. In the endoscopic surgery, there are various restrictions on the operation of the surgical instruments. Since the operation tool of the endoscope is operated with a trocar as a fulcrum, a distance to an organ in the abdominal cavity is necessary to expand the range of the motion in the abdominal cavity.

In the endoscopic images, it is necessary to take a large space in the body cavity in order to obtain a wide field of the view in the procedure region and the peripheral region. The pneumoperitoneum method [18], which secures a space with the carbon dioxide gas, is generally used to secure a space for operating the surgical tools in the body cavity. On the other hand, in the obstetrics and the gynecology, the lifting method that secures the space by lifting the abdominal wall with the device is also used. The pneumoperitoneum method is widely used because the carbon dioxide gas is inexpensive and relatively safe to enter the blood vessel, however the gas in the abdominal cavity is also sucked at the same time as the blood is sucked at the time of bleeding. There is a problem that the gas pressure decreases and the operating space decreases. Furthermore, when a large amount of gas is delivered into the body cavity, the pressure causes the veins to collapse, reducing the blood circulation, resulting in occurred cardiac output and atelectasis, which makes vital management during surgery extremely important [62,63].

The pneumoperitoneum is popular because it can easily secure the surgical space, but on the other hand, many studies have been conducted on the influence of pneumoperitoneum due to hypothermia caused by low-temperature gas and the type of gas. In the lifting method [19], there was a problem that there was an incision for passing the wire for raising, but the surgical method combined with the single incision endoscopic surgery with an incision of only the umbilicus has been proposed, the postoperative esthetics have been improved [64].

In the WaFLES technique, this surgical space is secured by an isotonic solution filled in the body cavity [60]. Since the liquid is circulated by the perfusion device, there is no change in the amount of the liquid in the body. Therefore, it is possible to secure a continuous surgical space.

There are the various good effects due to the presence of the liquid in the surgical space [60]. In the surgical room, the room temperature is constant at around 20 ° C, and the humidity is set to 50% or less. However, the temperature in the body cavity is about 38 ℃, which is close to the core body temperature, and the humidity is almost 100%. Due to the temperature difference, the tip of the scope becomes cloudy inside the body and the field of view deteriorates, and halation occurs because the surface of the organ is wet. Since the same problem occurs in the inspection using an endoscope, this problem can be avoided by putting the product for the purpose of anti-fog on the tip or the tip of the scope in the hot liquid. In the WaFLES technique, the tip of the scope is in the liquid environment, so it has an antifogging effect, and it is possible to avoid removal of the scope and reduce the surgical time and stress accompanying it.

In addition, based on the conventional endoscopic surgery, the incision is released to receive external stimuli such as drying due to the gravity, the pneumoperitoneum and the temperature difference. In the liquid, the luminal organs are buoyant by the air inside, and because they float in the heated liquid, the organs caused by the pneumoperitoneum do not fold up and the floating organs can be easily moved [60]. In the conventional endoscopic surgery, the field of view is expanded, and the surgical space is secured by squeezing the organ under gravity, but there is a risk of damage due to excessive force. Since buoyancy reduces the force required for towing, gripping and displacement can be performed with a smaller force than ever before, which is expected to contribute to the development of the new devices.

The hemostatic procedures during the endoscopic surgery differ depending on the blood vessel [65]. In the venous bleeding, the compression hemostasis using the gas pressure is possible during the pneumoperitoneum [66]. However, with this procedure, the gas that has entered the blood vessels may cause the embolism. In the pressure hemostasis due to the liquid pressure, there is no problem even if the liquid enters the blood, and the problem of stimulating the diaphragmatic nerve like the gas can be avoided.

In the arterial bleeding, an immediate hemostatic procedure using the electric devices are performed instead of the compression hemostasis [66]. In the conventional endoscopic surgery, there is a problem that the electric scalpel cannot be used if the bleeding point is hidden in the blood. Therefore, the hemostasis is performed by identifying the bleeding point by wiping and sucking the blood with a large amount of perfusate and wiping it with the gauze. The perfusion is also used to remove the red blood cells released after the hemostasis. In addition, the electric devices are devices that perform the incision, the hemostasis, and the coagulation by using the high-frequency arc discharge. At this time, the surrounding region may reach 100 ℃ or more, and hot gas may be generated, which may cause burns to the surrounding region [67]. In the liquid, the problem is avoided because the surroundings region cooled by the liquid. Since the temperature of the devices does not rise excessively in the liquid, it is thought that the tissue carbonization and the adhesion are suppressed.

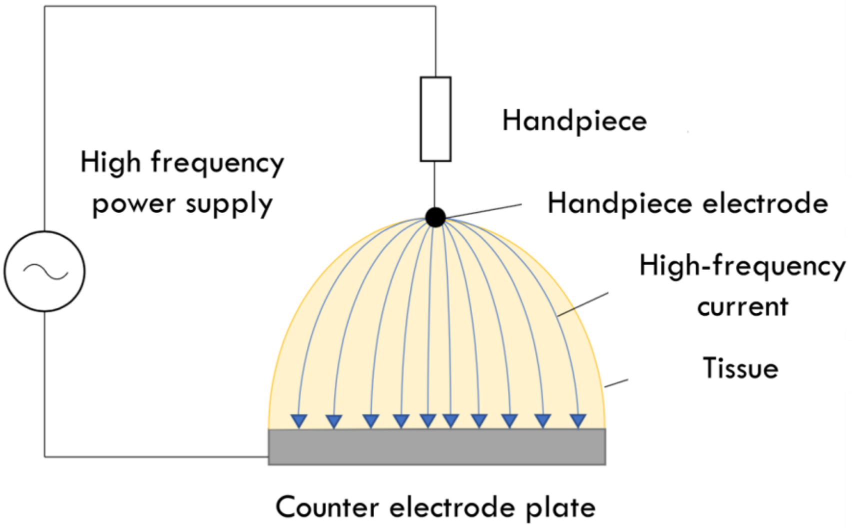

Fig.2.2 Mechanism of the monopolar electrode surgical knife.

The advantage of the WaFLES technique, such as the prevention of the desiccation of the internal organs, requires that the isotonic solution be sufficiently stored in the body. When pouring the liquid, it is necessary to store the liquid up to the edge of the incision. Therefore, the liquid leakage due to movement of the surgical tools during the procedure was a problem. It was necessary to take measures to prevent the leakage of fluid from contaminating the surgical environment. Since maintaining the visual field is an important issue for performing smooth the surgery in the liquid, it was an urgent task to establish an efficient perfusion environment.

2.3 Development of the cistern device for the WaFLES technique

In this Chapter, we developed the device aiming at establishing the WaFLES technique. We aimed to develop the device that solves the liquid leakage problem in the WaFLES technique and provides the procedure environment that allows the continuous observation of the bleeding site.

At this time, we defined the procedure environment in which the bleeding can be observed continuously. This required the rapid liquid replacement and the provision of the perfusion environment with a gentle flow with a controlled flow rate. Therefore, we focused on the influence of the flow passage area on the flow velocity.

When the liquid entered the body cavity, the rapid change of the area of the inflow surface was suppressed and the inflow area was increased. In this time, the following equation holds.

It is considered that masses of m_{in} and m_{out} come in and go out per minute time Δt. The temporal change ΔM at that time can be expressed as follows.

$$\Delta M = (m_{in} - m_{out})\Delta t \tag{2.1}$$

If the flow is steady, then $\Delta M = 0$.

$$m_{in} = m_{out} \tag{2.2}$$

Since the mass flow rate per unit time is the same, let each density be ρ_{in} and ρ_{out},

$$\rho_{in} v_{in} A_{in} = \rho_{out} v_{out} A_{out} \tag{2.3}$$

If the density is constant, we get the following Equation (2.4).

$$v_{in} A_{in} = v_{out} A_{out} \tag{2.4}$$

This is called a continuous equation [68], and means that the larger the cross-sectional area, the slower the flow velocity if the flow rate is constant.

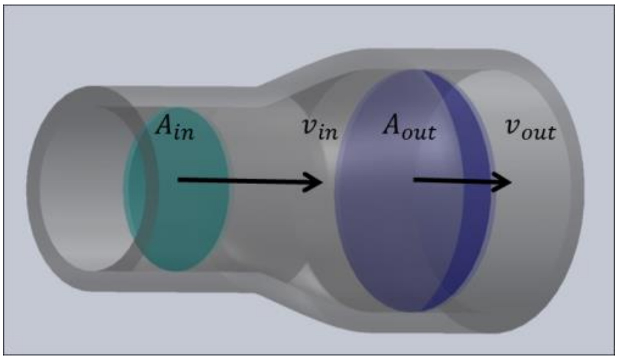

Fig.2.3 The relationship between change in flow velocity and flow rate.

The single incision was used as the inflow surface to secure a large liquid injection channel. We succeeded in making the incision the inflow surface by installing the cistern on the body surface [69]. In this way, we developed the device that can inject a large amount of the liquid at a time while suppressing the flow velocity and formulated the surgical procedure.

In order to prevent the liquid leakage, the incision retractor and the extracorporeal cistern [69] were integrally molded to prevent the liquid leakage significantly compared to the conventional WaFLES technique [60].

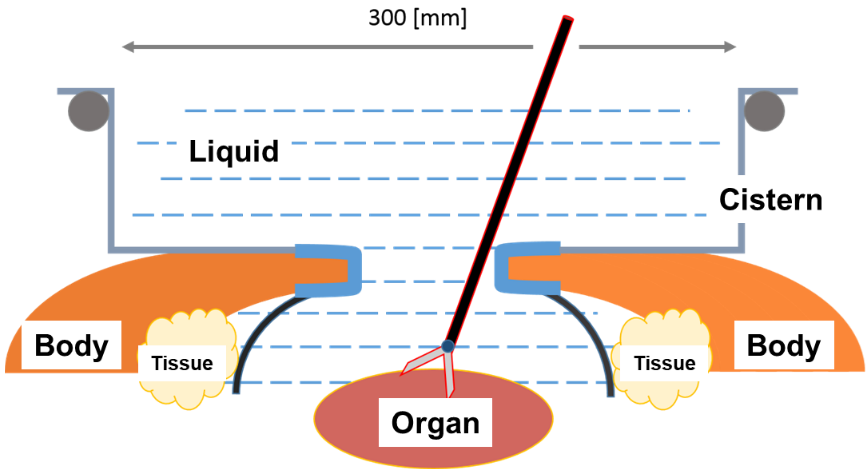

Fig.2.4 The cistern on the body surface [69].

Next, the device was tested by the animal experiments, the device specifications were formulated from an ergonomic point of view [70]. The size of the cistern device was designed so that enough range of the doctor's motion could be secured with reference to the movement of the surgical tool. We used the Thompson retractor system to install and maintain the cistern device.

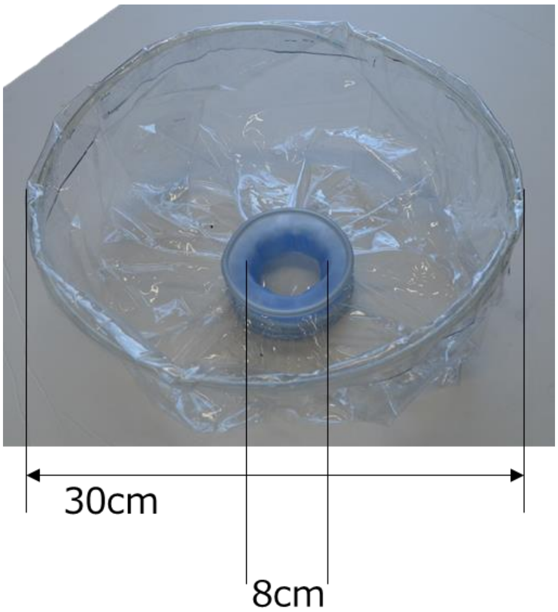

Fig.2.5 The size of the cistern device.

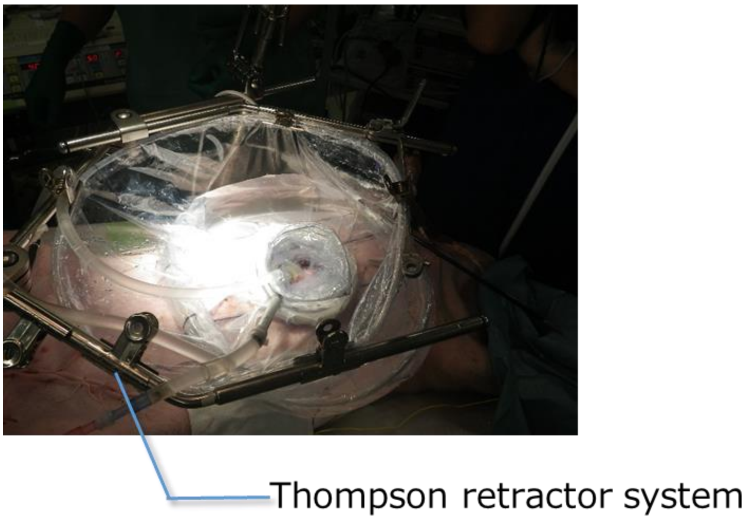

Fig.2.6 The installation and maintenance of the cistern device.

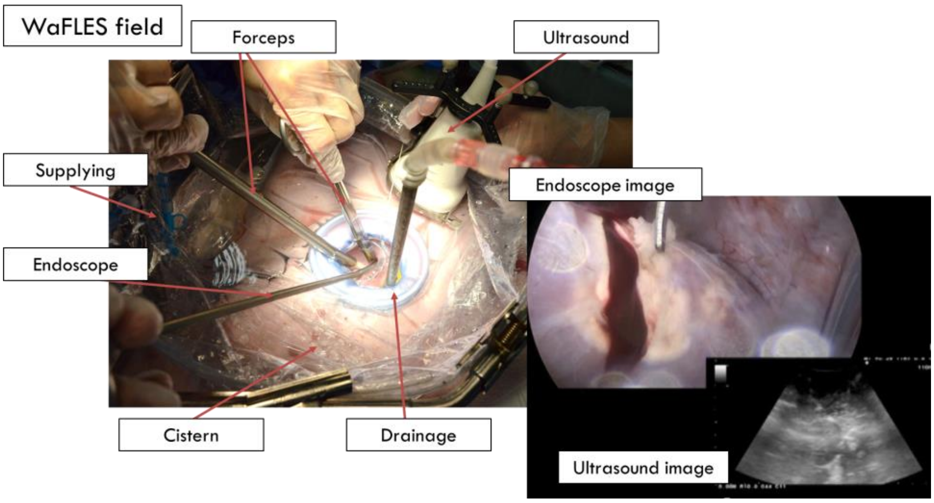

Fig.2.7 The animal experiment using WaFLES technique [71]

As the results, the good field of view was ensured under the perfusion environment and the bleeding point was visually recognized, the surgical procedure was completed by the doctor, and the surgical environment due to leakage was obtained [71]. The prevention of contamination was confirmed. Furthermore, it was suggested that it was possible to develop the new surgical method, such as the real-time acquisition of ultrasonic images during the surgery.

The device installation time was measured to verify the practicality of the cistern device developed in the four animal experiments. As the results, the installation time were about 5 to 7 minutes (Fig.2.8). According to the two doctors, the installation of the cistern device did not interfere with the procedure.

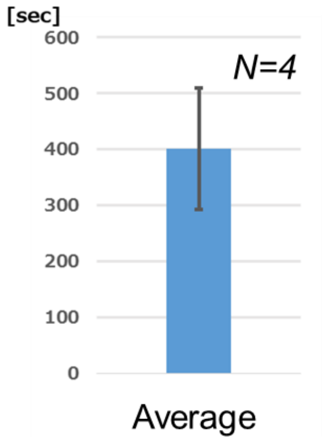

Fig.2.8 The installation time of the cistern device

Moreover, with the conventional WaFLES technique, the irrigation rate of 300 ml/min was the limit, but the cistern device we developed enabled irrigation up to 2000 ml/min. No major the liquid leaks occurred at this time, and the surgical environment was not contaminated. The amount of the liquid used in the WaFLES technique was reduced by 50% or more compared to the conventional WaFLES technique using the trocar device.

In addition, when an ischemic nephrectomy was performed with a retroperitoneal approach, the vertical distance of about 80 [mm] and the about 110 [mm] distance up to the surgical field were secured and maintained by the liquid irrigation (Fig.2.9). As the results, we completed the procedures of non-ischemic nephrectomy and nephrectomy in four animal experiments. According to the two doctors who performed the surgery, sufficient space for surgery and maintenance of the visual field by the blood washing based on the liquid irrigation were able to be maintained.

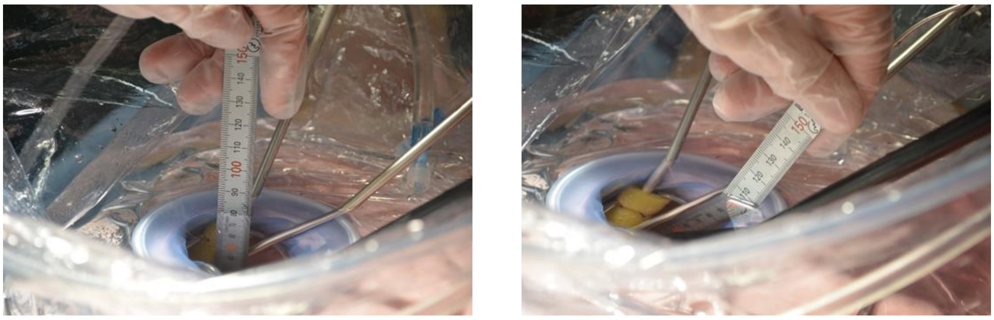

Fig.2.9 The secured space by WaFLES technique

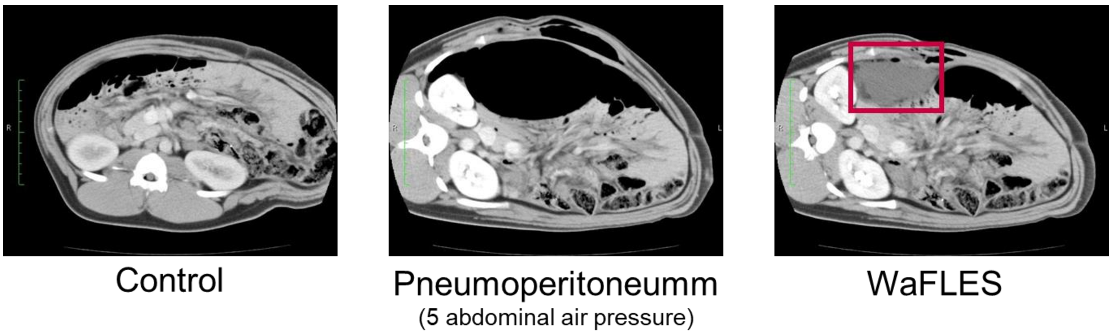

Fig.2.10 The comparison using the CT images when securing the surgical field (The red frame in the WaFLES's CT image is the operative field space in the liquid by the WaFLES technique)

Then, using the cistern device, we observed the surgical field region secured by the WaFLES technique, the surgical field region secured by the pneumoperitoneum method, and the surrounding tissues using the CT images (Fig.2.10).

The CT images in Fig. 2.10 were selected by the doctor as the images of the abdominal cross section at approximately the same position. When comparing the pneumoperitoneum method and the WaFLES technique, the space secured by the pneumoperitoneum method was smaller in the WaFLES technique. However, as mentioned above, there was no problem with the WaFLES technique in performing the procedure, so it was considered that there was sufficient space for performing the procedure. On the other hand, the pneumoperitoneum method can secure the large surgical field space, but it was observed that the normal tissue was compressed by the pneumoperitoneum pressure. The doctors pointed out that compression of the organs could lead to the adhesion and inflammation between the organs. Therefore, it was suggested that the WaFLES technique, which could maintain the environment close to the normal state of the body cavity, was more minimally invasive than the conventional pneumoperitoneum method even if the surgical field space was secured. This was considered to be the proof of the improvement of minimally invasiveness by maintaining the physiological environment in the body cavity, which was the advantage of the WaFLES technique described above. In other words, it was considered that the provision of the WaFLES technique using the cistern device that we developed was less invasive than the conventional pneumoperitoneum method.

・The limitations of the current study and the future works

In this chapter, we developed the device to provide the stable WaFLES technique environment and evaluated it by the animal experiments. However, it has not been possible to quantitatively show the rectification environment in the body cavity and the state of the liquid flow in the WaFLES technique baced on the developed device and the conventional WaFLES technique. Therefore, in order to show the usefulness of the developed device, it was considered necessary to visualize and quantify the flow in the body cavity. For this purpose, the methods that incorporates the flow simulating the inside of the body cavity and the development device, mixes markers in the liquid, observes the movement of the markers with an endoscope, and calculates the amount of movement is considered.

Furthermore, the developed device stabilizes the provision of the WaFLES technique for the partial nephrectomy, nephrectomy and cystectomy. Therefore, it is considered necessary to develop the device adapted to other surgical fields and lesions. In addition, the provision of the WaFLES technique by the developed device facilitates visual recognition of the bleeding and the bleeding points during nephrectomy. Therefore, the development of basic technology aiming at effective hemostasis support and integration with robot technology is described in the following chapters.

2.4 Brief Summary

In this chapter, we worked on the device development to realize the procedure environment under the liquid which can maintain and improve the QoL of the patient more than the conventional endoscopic surgery. To establish the environment for the WaFLES technique, we have developed the extracorporeal cistern for the purpose of maintaining the visual field for the bleeding during the surgery and the preventing surgical environment pollution due to the liquid leakage. The blood flow can be removed and recovered by preventing the rapid flow velocity and the diffusion flow from flowing into the surgical field during the bleeding, enabling continuous observation of the bleeding points. The usefulness of the device that realizes a gentle flow using the incision is suggested. In the animal experiments using the WaFLES technique, the visual field was maintained even during the arterial bleeding, and the usefulness of securing the visual field with the device was confirmed. This suggests that the problems of the conventional WaFLES technique, such as the deterioration of the visual field for the bleeding and the problem of the liquid leakage, could be solved by the external cistern. It was thought that this would provide the patients with the procedure environment that is less burdensome than the conventional endoscopic surgery. In the next chapter, based on these results, we developed the elemental technology of the surgery assistant system for the doctors using the observation of the persistent and stable bleeding points, and aimed to reduce the burden on the doctors.

Chapter 3 Development of detection method for automatic hemostasis using machine learning with abdominal cavity irrigation

3.1 Introduction

Minimally invasive surgery—performed by inserting an endoscope and the surgical instruments into the body cavity through small incisions to improve a patient's quality of life (QoL)—is commonly used in many surgical fields. This procedure provides several benefits to the patients by shortening, both, the degree of postoperative pain and the period of recovery. Furthermore, a previous study [60,71] that focused on anticancer and organ function preservation effects proposed a method of securing a new surgical space with an aim of obtaining results that surpass those of laparotomy in the conventional minimally invasive procedure. In this system, the surgical field is filled with an isotonic solution of approximately the osmotic pressure of the

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[100] Matsunaga Y, Nakamura R, Development of detection method for automatic hemostasis using machine learning with abdominal cavity irrigation, International Surgery Journal, 2020;7(7):2103-2109, 2020.

living tissues instead of gas and surgery is performed in the liquid (WaFLES) [60,71]. This liquid surgical technique is majorly used in the field of urology due to its high safety and low invasiveness [72]. Currently, major surgical procedures under water are often performed within narrow lumens. However, the WaFLES technique can be performed in the wider abdominal, pelvic, and retroperitoneal cavities. Therefore, the demand of skills on the doctors is very high [71], which increases the burden on doctors. To reduce the burden on doctors, assistance is provided by medical robots [73] and navigation systems using medical images [74]. We focused on the clear view provided by the WaFLES technique, which is one of its advantages. Endoscopic images under irrigation have better appearance of bleeding than those with the use of a gas [71]. Furthermore, hemostatic procedure is an important surgical procedure. Especially in hemostasis in liquid, the coagulation is softer than that in gas, and the clinical skill required is very high due to the low invasiveness [75]. Therefore, we aimed at developing a system for assisting and automating the hemostatic procedures. We began by assuming that it is important to identify the bleeding points at the beginning of the surgery in order to assist and automate the hemostatic procedure. At the end of the procedure, it may be necessary to detect the regions of hemostasis because of the application of an energy device to an organ. The purpose of study was to devise a means of detecting organs, bleeding points, and hemostatic regions using the advantages of the endoscopic view provided by the WaFLES technique.

In this paper, we have provided the WaFLES technique that enables stable observation of hemorrhage during partial nephrectomy. Therefore, we focused on the development of basic technology for implementing the new and effective hemostatic technique. The development of the region detection method in this chapter was the first step in the development of this basic technology.

3.2 Detection method of our three regions of organ, bleeding, and hemostasis

・Our system design and plan of the detection method

Recently, with the declining birthrate and aging population, the doctors do many jobs every day. The workload of the doctors is increasing. However, it is difficult to quickly increase the number of doctors. Therefore, by automating part of the doctor's work with a robot, the workload is reduced and the burden on the doctor is reduced. Furthermore, it was thought that automation of medical care would contribute to the reallocation of human resources in hospitals and improve the working environment for the doctors.

In this paper, we focused on the hemostatic technique, which is one of the surgical treatments, and conducted the research toward automation. The hemostatic procedure consists of detection of bleeding within the surgical area and coagulation of the bleeding tissue with the application of an energy device. Based on this mechanism of hemostasis using an energy device, a part of the system necessary for assisting and automating the hemostasis procedure has been depicted in Fig.3.2. We focused on constructing a method of detecting the bleeding and hemostasis regions, which is the most important factor in our system. The bleeding and hemostatic regions have various shapes and edges on the images. Therefore, we developed a detection method using machine learning with a focus on the change in color information due to the energy device. Studies on the detection of bleeding in endoscopic images have been based on the color feature descriptor [76,77], texture feature descriptor[78,79], and edge feature descriptor[80-82] in the field of diagnosing using wireless capsule endoscopy. In a previous study [83] aimed at assisting the hemostasis procedure, the authors used a bleeding region detection method in endoscopic surgery with a focus on detection accuracy and calculation cost of a linear support vector machine (SVM) [84] based on the color feature descriptor. However, previous studies did not attempt to detect the hemostatic region. Therefore, in order to develop our system, we constructed a method of detecting three regions: the organ region, bleeding region, and hemostatic region. We adopted region detection using linear SVM with multiple color feature descriptors, while maintaining the real-time property and detection accuracy.

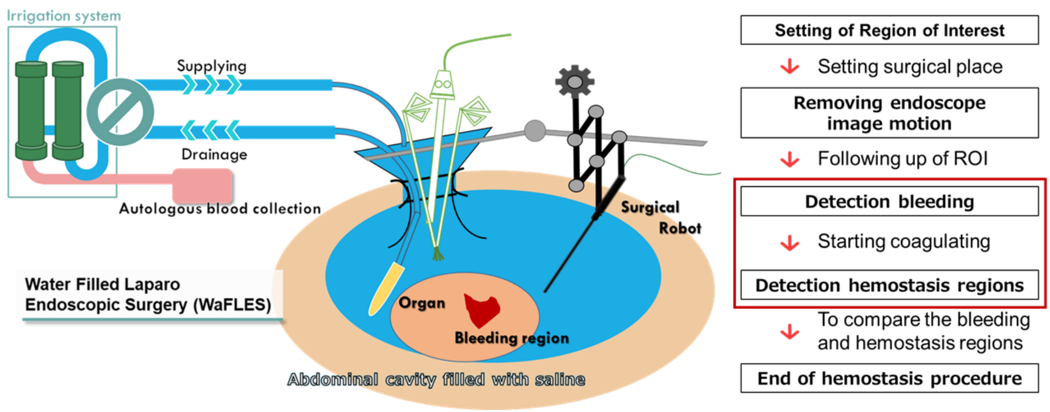

Fig.3.2 Proposed surgical robotics system design and workflow of our proposed hemostatic system using WaFLES technique.

・**The linear SVM and the multi-classification**

The SVM method is a statistical classification method using machine learning. The focus point was that the higher accuracy classification was possible using a few feature descriptors than the other method using machine learning so it was could reduce the calculation cost. It was a suitable method for us aiming at real-time classification. The SVM classifiers were applied by calculating the best hyperplane using data points [84]. In general, hyperplanes are treated as optimization problems, as shown in Equation 3.1.

$$\arg min_w \frac{1}{2}|w|^2 + C\sum_{n=1}^{N}\xi_n$$

$$s.t.\ t_n(w^T\varphi(x_n) + w_0) - \xi_n \geq 1 \tag{3.1}$$

where w is the gradient of the hyperplane, w_0 is the intercept, t_n is the label corresponding to data point x_n, C is the parameter that determines the tradeoff between the penalty and the margin [84], ξ_n is the slack variable [84], given as:

$$\xi_n = | t_n - (w^T \varphi(x_n) + w_0)| \tag{3.2}$$

and $\varphi(\cdot)$ is the kernel function. In the linear SVM, the kernel function is applied to Equation (3.3).

$$\varphi(x_n) = x_n \tag{3.3}$$

In general, Lagrange's undetermined multiplier method is used to solve the minimization problem of Equation (3.1). In this study, we used the sequential minimal optimization (SMO) [85] algorithm. When a new x_n is given, y is obtained as follows by solving the optimization problem:

$$\mathrm{y} = w^T x_n + w_0 \tag{3.4}$$

In Equation 3.4, linear SVM classification was performed according to the sign of y when a new x_n was given. In our study, we tried multiclass classification, which has not been done in previous studies. We used the multiclass model [85] that does binary classifications as necessary of number.

・**The selecting the color feature descriptors**

Based on previous research, we began by selecting the color feature descriptors. Then, we focused on the sharpness of the endoscopic images in the liquid because the contrast between S value and V value in the HSV model which was the hexcone model [86]. These values were the better in liquid than in gas. Previous studies have demonstrated the usefulness of the S value in the detection of bleeding regions. Furthermore, the color information of the hemostatic region in the endoscopic image in liquid was investigated, and the color information of the organ region that was believed to be incorrectly identified as the hemostatic region was randomly extracted at 256 pixels. Subsequently, the contrast in the V value tended to be different between the organ and hemostatic regions. Furthermore, it was found that by adding the S value used in previous studies, each value demonstrated a high value in the hemostatic region (Table 3.1).

Table 3.1 The results of S and V values.

N=256	**Organ**	**Hemostasis**
S(mean±SD)	0.18±0.05	0.19±0.02
V(mean±SD)	0.69±0.19	0.88±0.07

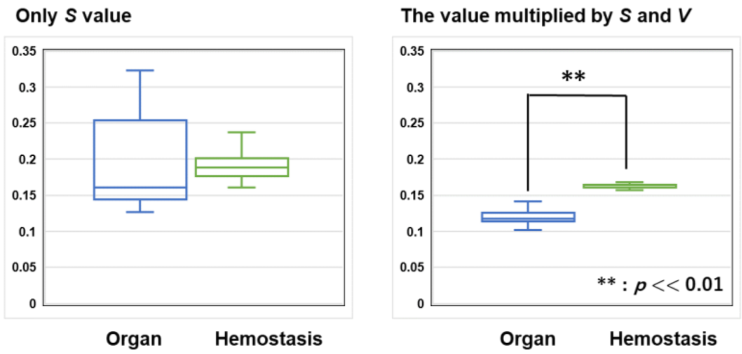

Fig.3.2 Comparison between S value only and S multiplied by V.

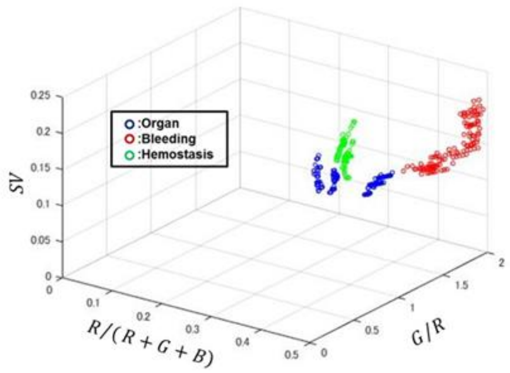

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Fig.3.3 Descriptor in 3D space.

Therefore, we thought that by multiplying the S value and the V value, it becomes easier to distinguish the organ region and the hemostasis region than the S value alone. In the Figure 3.2, we compared the S value only and the product of the S value and the V value in the organ and hemostasis regions. In the Fig. 3.2, Mann-Whitney U-test showed that no significant difference was found only with S value at a significance level of less than 0.5. In the other hand, the product of the S value and the V value, the significant difference of less than 0.01 was confirmed. As the result, it was considered effective to use the value obtained by multiplying the S value and the V value in the discrimination between the organ region and the hemostasis region.

From the viewpoint of calculation cost, it was considered that up to three color feature descriptors would be good; therefore, we used a new descriptor F_3 (Eq. 3.5) that was obtained by adding the V value to the color feature descriptors proposed in the conventional method[83] in order to improve the detection accuracy of the hemostatic regions. Equation 3.1 summarizes the color feature descriptors proposed in this paper.

$$F_1 = R_{(i)}/(R_{(i)}+G_{(i)} + B_{(i)})$$

$$F_2 = G_{(i)}/R_{(i)}$$

$$F_3 = S_{(i)}V_{(i)} \tag{3.5}$$

where, $R_{(i)}$, $G_{(i)}$, and $B_{(i)}$ were the RGB values and, $S_{(i)}$ and $V_{(i)}$ were the saturation and lightness at the i^{th} pixel. In Equation 5, the descriptors F_1 and F_2 were adopted from previous studies [78,83] because we thought they would contribute to the detection of bleeding region. The descriptor F_3 was a newly proposed descriptor in this paper because we thought it was effective in detecting the hemostasis region.

・The create dataset and verification of SVM classifier

Our training database was created. The objects were endoscopic images of partial non-cancerous nephrectomy specimens in three animal experiments specific pathogen-free pigs weighing about 30 kg performed by urologists using WaFLES with the approval of the local ethics committee for animal experiments. In the experiment, the endoscope was manually fixed. Our dataset was recorded with an endoscope (KARL STORZ, IMAGE1™ Camera System; 30 fps, 1920×1080). From three animal experiments with different lighting, we obtained a total of three hemostatic procedures, for example one of the hemostatic procedures shown in Fig.3.4. Under the guidance of a urologist, we obtained the ground-truth label from 90 images, 30 images from each hemostatic procedure. From these endoscopic images, pixels of organs, bleeding, and hemostatic regions were randomly extracted at 106496 pixels, totaling 319488 pixels (Fig.3.4).

Fig.3.4 Target regions (white triangles) obtained from the endoscopic videos in the WaFLES technique.

After that, the linear SVM classifier was learned by our training database and verified by the stratified five-part cross-validation. In cross-validation, we used the KFold method [87]. The cross-validation is used to evaluate the generalization performance of the learning model. In this paper, the SVM classifier was sufficiently generalized with stratified five-part cross-validation, and then the prediction accuracy was evaluated. In verification, the true positive (TP), false positive (FP), true negative (TN), and false negative (FN) rates were calculated from the rate of the pixels classified in each region. The accuracy was obtained according to Equation (3.6):

$$\text{Accuracy} = \frac{TP + TN}{TP + FP + TN + FN} \tag{3.6}$$

By comparing the SVM classifier using our descriptors with the conventional descriptors [83], the accuracy level of the SVM classifier was guaranteed using our training database.

We applied the SVM classifier to images not included in our dataset and confirmed detection accuracy based on the ground-truth label created by a urologist.

・**Evaluation of the calculation cost and our detection system**

In order to calculate the cost of our SVM classifier, the processing time was measured by adapting to endoscopic images of 720 × 480 pixels. Our classification was implemented using a computer with Intel Core i7-6700K (4.00 GHz 4-core/8- thread CPU) and 16.0 GB RAM. OpenMP was introduced to run in multi-thread mode based on the CPU. The programming language used was C / C ++.

As part of the verification of the effectiveness of our method, we set the region of interest (ROI) manually in the endoscopic images of non-ischemic partial nephrectomy using the WaFLES technique in an animal experiment. Subsequently, areas of bleeding by ablation and hemostasis by coagulation using the energy device were detected, and changes in each region size and effects of the procedure on the endoscopic image were compared.

3.3 Results

The evaluation of the prediction accuracy of the classifier using our descriptors revealed that the classification accuracy was 98.3%, which was better than that with the conventional descriptors (95.6%) [83]. Fig.3.5 demonstrates the confusion matrices and TP and FP rates of each region in the classifier using our descriptors and the conventional descriptors.

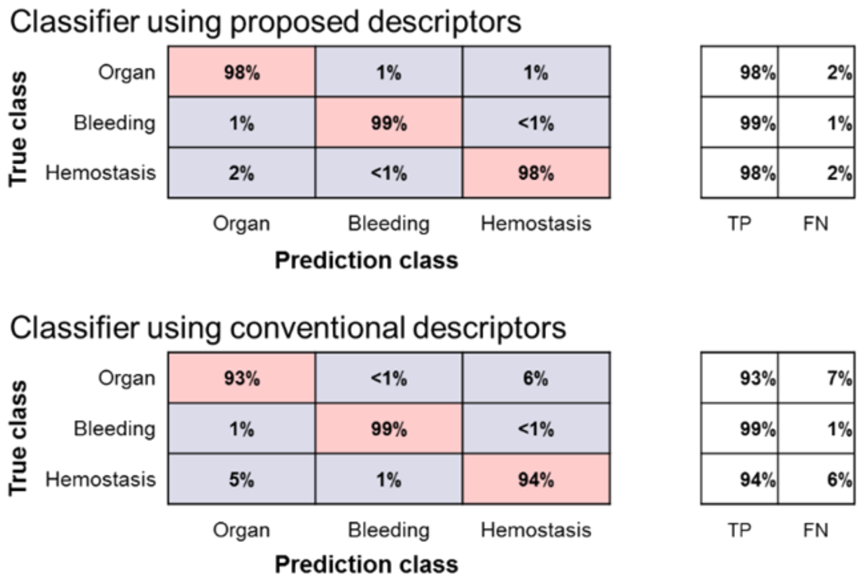

Fig.3.5 Confusion matrices and TP and FN rates in each region.

Figs. 3.5 and 3.6 summarize the frames of visualized images of the classification results based on our method with the green region indicating the bleeding region and the blue region indicating the hemostatic region. Fig.3.6 summarizes the cases of organ and bleeding regions alone, and the organ and hemostatic regions alone. Fig.3.7 summarizes the results with coexisting organ, bleeding, and hemostatic regions.

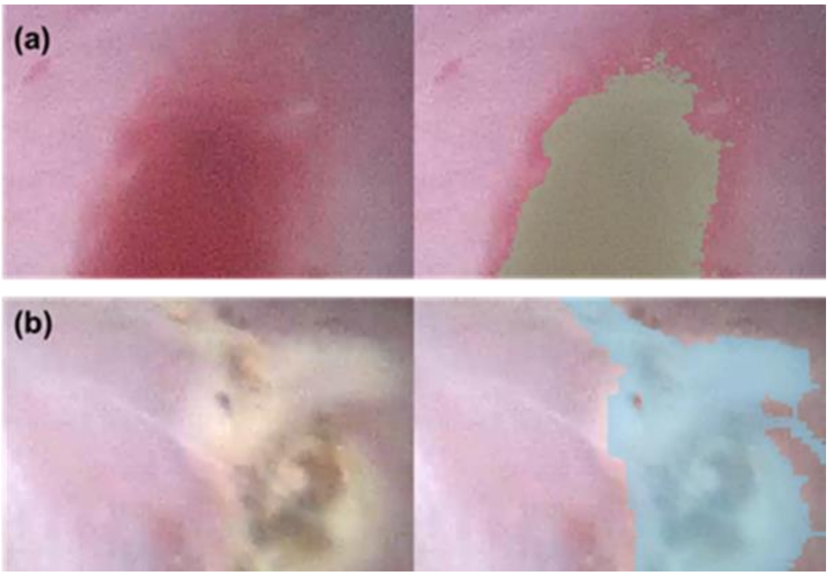

Fig.3.6 Detection and visualization of (a) the organ and green indicating the bleeding region and (b) the organ and blue indicating the hemostatic region.

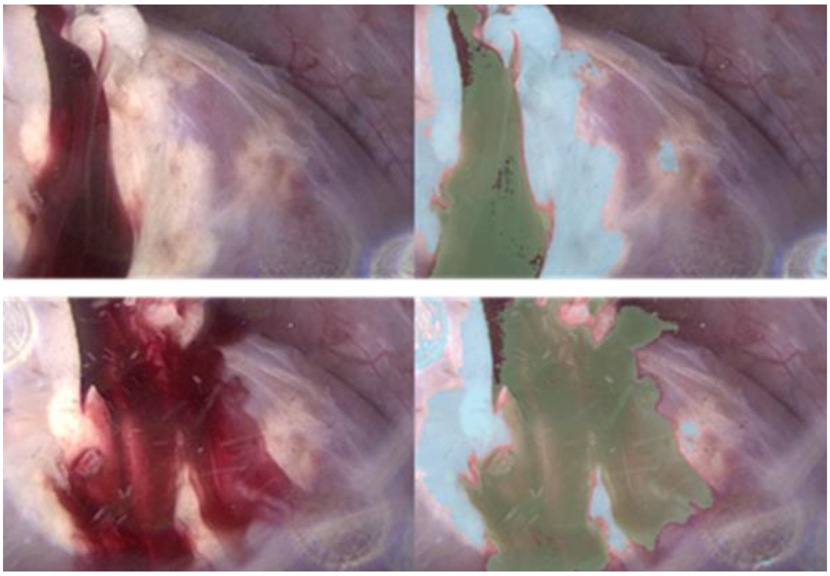

Fig.3.7 Detection and visualization of coexisting organ, bleeding, and hemostatic regions.

Regarding the calculation costs, the processing time was 21.6 ± 0.6 (mean ± standard deviation, SD) [ms] (N = 10).

The verification results of the effectiveness of our system (Fig.3.8) demonstrated ROI (400 x 400 [pixel]) used for verification then, the surgical procedure proceeded in time series from label 0 to 7 in the image.

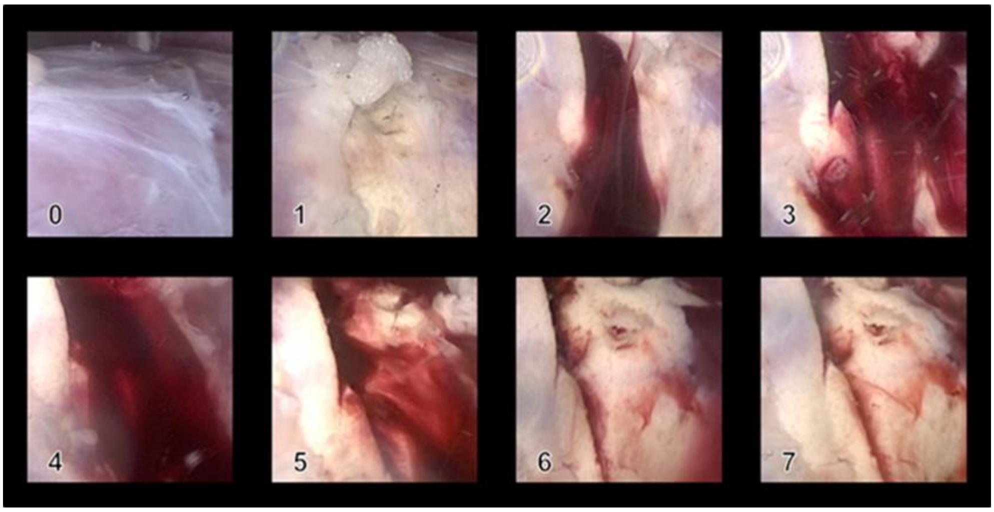

Fig.3.8 Procedure events on endoscopic images between time series 0 and 7.

At this time, our method was applied and the change in the size of each region in the image was evaluated (Fig.3.9).

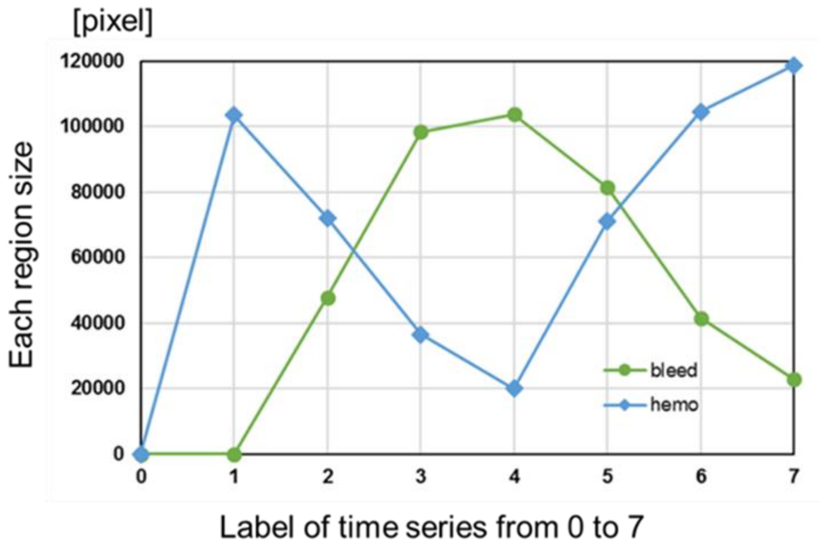

Fig.3.9 Changes in the size of each region using images of Fig.3.8 time series from 0 to 7.

3.4 Discussion

In this Chapter, in addition to the detection of bleeding region, a new real-time system incorporating a three-region classification method of endoscopic images and defining the hemostatic region was proposed.

・Detection using our descriptors

Previous studies have proposed region detection using linear SVM based on calculation cost and the detection accuracy of the bleeding region. A new color feature descriptor was proposed using the S and V values in the HSV model of identifying the bleeding region in a liquid because in addition to the characteristic color features in the hemostatic region, we considered that the higher clarity of the endoscopic images in liquid would have an effect as well. An endoscope has a very strong light source at its tip. Therefore, when gas is used, the light is reflected more frequently over organs and tissues, and halation is likely to occur, thereby, decreasing the contrast of the images. Compared with gas, the there is a tendency for light to diffuse more in liquid and, thus, high contrast can be achieved. The contrast between the S and V values in liquid become high since the saturation and lightness in the HSV model are susceptible to the lighting environment, and we believe that the proposed color feature descriptor contributed to the classifier in the hemostatic regions. In comparisons between the conventional color feature descriptors and the matrixes of our color feature descriptors in the results of the evaluation of the prediction accuracy, our classifier's distinction between the organ and hemostatic regions was better. Therefore, we believe that that the three-region classification using our color feature descriptors is useful and has enough accuracy (Figs. 3.5, 3.6).

・**The measurement of calculation cost**

It was possible to process approximately 21 ms of an endoscopic image of 720 x 480 pixels; therefore, our classifiers are adaptable to the general 30-fps endoscopic videos. In this study, parallel processing on the CPU was performed, which was feasible with a general use computer. In order to further improve the processing time, various possibilities such as image processing based on GPU were considered. Ultimately, verification of the processing time when running the workflow, as shown in Fig.3.2, was considered necessary.

・**Evaluation our detection system**

In the verification results of the effectiveness of our system (Fig.3.8), we picked the same area on which the procedure was performed using manually set ROI. Fig.3.8 (0) demonstrates the initial state of the organ, and the bleeding and hemostatic regions were not detected in the 0th label of Fig.3.9. Whereas, Fig.3.8 (1) demonstrates that the surface of the organ was coagulated with an energy device, and the hemostatic region was detected with the 1st label in Fig.3.9. In Fig.3.8 (2), the ablation of the organ was performed using forceps, and it was understood that bleeding was occurring along; subsequently, the detection of the bleeding region is shown on the 2nd label in Fig.3.9. Furthermore, the size of the hemostatic region was decreased since the bleeding was flowing on the anterior surface of the coagulated organ. In Figs. 3.7 (3–7), we confirmed that the hemostatic procedure had started. The peak of the size of the bleeding region was confirmed with the 4th label in comparison to the 3rd label in Fig.3.9 since multiple episodes of bleeding occurred at the beginning. The bleeding stopped as time passed after the hemostatic procedure was performed [Figs. 3.7 (5–7)]. The mechanism by which the size of the hemostatic region increases was quantitatively defined by the change in the value of the 7th label in comparison to the 5th label in Fig.3.9. Therefore, it was demonstrated that the detection of bleeding and hemostasis by energy device could be performed in our system by monitoring the ablation and coagulation areas.

・Benefits of minimally invasiveness and reduction of the burden by our detection

In the WaFLES technique, by gentle irrigation, the distribution of blood was not diffuse, and the bleeding points could be stably observed. Furthermore, it was easy to detect the state change of organs by the hemostatic technique since it was easy to observe the hemostatic regions. Even when gas is used, the surgical field is cleaned often [88-90]; therefore, it is possible to apply our system in environments like that in the WaFLES technique. Furthermore, the detection of the hemostatic region can result in the possibility of making the procedure less invasive. There are multiple studies on reducing the invasiveness of tissue coagulation by energy devices [91-93] because tissue coagulation by energy devices often causes loss of normal tissue. Many studies have attempted to minimize the invasiveness of tissue coagulation by controlling the output of the device. Therefore, by introducing our system, it is possible to provide feedback to the coagulation device and reduce the invasiveness by monitoring the bleeding region and quantitatively judging that hemostasis is complete. Moreover, real-time detection of bleeding and hemostasis regions would assist doctors and provide safe and the burden less surgery for doctors.

・**The limitations of the current study**

In our system, we detected the bleeding region on endoscopic images in real-time and quantified the size of the region as well. Furthermore, processing the data while excluding the motions of the endoscope and the organ were required for tracking the ROI setting. The solutions included adapting the self-position estimation method [94] of the endoscope, extraction of the endoscope motion by the three-dimensional position measuring device and calculating the optical flow [95] using landmarks in the image. Therefore, our future work will be focused on guiding the surgical robots to the detected bleeding region and based on the feedback from the hemostatic procedure and alert from the bleeding region and the hemostatic region quantitative evaluation shown. These advancements can help automate the assistance and evaluation of the system. Furthermore, we had to develop the robot hardware and integrate our system to automate the procedure and evaluate its performance. These would be of great interest to our study in the future.

The purpose of this study was to detect the bleeding region and not to identify the bleeding point. However, it was considered necessary to identify the bleeding points when the robotic technology and the assistance doctors.

In order to identify the bleeding point, it may be possible to estimate it from the endoscopic image using the field of view by the excellent WaFLES technique, based on the image differences. The identification of the bleeding points is an issue that should be investigated in the future.

・The contribution to expected medical environment

The system that incorporates our detection method has been considered to assist or automate the hemostatic procedure of the doctors. For example, it was considered possible to automatically detect and notify the doctor when bleeding occurred outside the surgical view where the doctor was paying attention. It was also considered that by combining with the medical robot, the small amount of the bleeding etc., could be left to the robot, and the doctor could concentrate on more serious procedures. However, such the surgical environment is not currently recognized. Therefore, it was thought that if the attempt to automate the procedure as in this research became popular and could be used clinically, it would be possible to provide a new surgical environment and create the medical demand.

3.5 Brief Summary

We have proposed a system for automation and assistance in hemostatic procedures. Real-time region detection of the hemostasis procedure by linear SVM was realized by newly adding identification of the hemostatic region. In our method, we used the new color feature descriptor and focused on the change in the color information in the endoscopic images due to bleeding from organs and tissue coagulation due to energy devices. The accuracy of the classifier was 98.3% and the processing time was approximately 21 ms in images of 720 × 480 pixels; therefore, it was possible to detect three regions on endoscopic images of the hemostatic procedure using our method in real-time. Additionally, by measuring the bleeding and hemostatic regions during the hemostatic procedure in time series, assistance can be provided to the doctor by annotating the end of the hemostatic procedure. Moreover, it could contribute to reduce the invasiveness by reducing the coagulation of normal tissues using energy devices. In the next chapter, we describe the analysis of the bleeding and hemostasis regions and the determination of the end of hemostasis procedures using our regions detection method.

Chapter 4 Analysis of the hemostasis procedure using the endoscopic images based on the machine learning for automatic hemostasis

4.1 Introduction

In the medical field, minimally invasive surgery (MIS), which is performed by inserting miniaturized tools and an endoscope into the body cavity, is widely used to improve the quality of life (QoL) of patients [96]. However, the burden on surgeons tends to increase, because MIS requires them to have higher skills than those required for conventional surgeries. In general, the introduction of automated systems and robotics technology is effective in reducing the burden on surgeons [97]. Some studies have proposed the cooperation of robotics with surgeons for MIS [60,73].

Improving the QoL of patients and reducing the burden on surgeons are major issues in medical engineering. Therefore, we focus on a new surgical procedure, water filled laparo-endoscopic surgery (WaFLES) [71,72], that

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Published paper on this chapter

[103] Matsunaga Y, Nakamura R, Analysis of Hemostasis Procedures through Machine Learning of Endoscopic Images towards Automatic Surgery, Sensors and Materials, MYU Tokyo, 2020;32(3):947–958, 2020.

uses liquids instead of the conventional gas to secure the space inside the body cavity. The surgery in liquids is commonly performed on narrow lumen organs such as the transurethral resection [90]. The WaFLES technique can be used to perform surgery in a large space by irrigating the liquid. By suppressing the cooling effect of the liquid and dryness of the organ, organ inflammation is suppressed [98]. This considerably contributes to improving the QoL of patients. In addition, the vision of the endoscope in the liquid under irrigation is better than when using conventional gas [72]. Further, by washing the organ surface, the treatment site and bleeding point can be constantly observed; therefore, sensing through endoscopic images is suitable.

In robotics, systems that detect targets and measure state transitions, converting them into digital data, are the important technical factors. In a previous study, we proposed and developed a system that can automatically detect the organ region, the bleeding region, and the hemostasis region in real time to assist hemostatic procedures [91]. Hemostasis are frequently performed in surgical procedures [75,92] such as the tumor ablation or the tissue dissection; therefore, robot assistance or automation can considerably reduce the burden on the surgeon. In addition, hemostasis performs the thermal degeneration of organs using energy devices [93,99]. Robots capable of highly accurate maneuvers can be expected to suppress invasion compared with humans, because the energy device can be guided to the correct place and the coagulation error can be reduced. The method developed by us in a previous study [100] contributes to the automation of hemostatic procedures by detecting changes associated with the protein degeneration of organ surfaces by using energy devices, from the color features of endoscopic images through the machine learning. In this method, we used the support vector machine (SVM) which was one of the machine learning methods. Machine learning can reduce the computational cost of the image processing and obtain high accuracy; therefore, it is widely used in the detection of bleeding regions for endoscopy [76-83]. Attempting to automate hemostasis procedures is a new study, because it is difficult to detect the hemostasis region, so we proposed the detection system [100] for the hemostasis region. In the present study, we analyzed the bleeding and hemostasis regions measured from endoscopic images using our detection method to clarify the termination condition of the procedure in automated hemostasis procedure.

4.2 Analysis method of the hemostasis procedures

・Proposed surgical system

The bleeding is frequent in surgical procedures because of the ablation of organs and tumors. The mechanism of hemostasis begins with the detection of the bleeding region [99]. The bleeding region tends to have various forms and textures in endoscopic images. Therefore, we proposed a detection method based on machine learning that focused on the color feature descriptor [76]. In our system, high accuracy real-time detection [100] was considered because the robot needed to coagulate while tracking the detected bleeding region. In addition, the heat-treated bleeding region was discolored owing to protein degeneration. We considered that the end of hemostasis could be determined by comparing the hemostasis region with the bleeding region, because the discolored region can be detected as a hemostasis region. Figure 4.1 shows an automated hemostasis robotic system that uses the WaFLES technique.

In this study, we extended the machine learning dataset in our previous study [100], to make the detection of the organ, bleeding, and hemostasis regions more robust. Furthermore, the end of the hemostasis procedure was analyzed by the rate of the bleeding region sizes and the hemostasis region sizes, and we tried to quantify the termination condition. We established the construction method of the sensing system for our surgical robot system by integrating the detection and analysis.

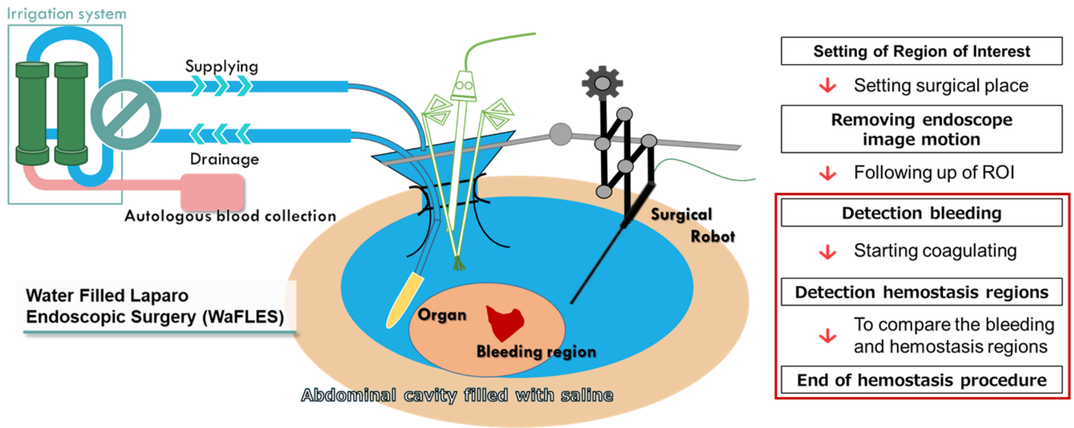


Fig. 4.1 Proposed surgical robotics system design using the WaFLES technique.

・Linear SVM method and multi-classification

The SVM method [84] is a classification method using prior learning based on the training dataset. The SVM method can obtain high classification accuracy using a few descriptors, and the computational cost is lower than that of other machine learning methods. The learning of the SVM classifiers is an optimization problem for hyperplanes.

In this Chapter, we attempted multiclass classification. We employed the multiclass model [85] that performs binary classifications as necessary of number of classifications. We used MATLAB® R2018a (Mathworks, Inc., Natick, MA, USA) to develop the SVM classifier and classify the regions.

・**Color feature descriptors**

Based on our previous study, endoscopic images in liquid had better contrast than when gas was used, because it provided the washing effect and soft lighting that moderately diffused the forward light in the surgical area. Therefore, in addition to the color feature factor in the conventional [83] RGB model, we proposed color feature descriptors based on the saturation (S) and lightness (V) values in the HSV model [86], which is the hexcone model [86]. It provides higher accuracy than the conventional method [83]. We used three color feature descriptors suitable for real-time processing (Equation 3.5).

・**Training dataset and SVM classifier verification**

A training dataset is required to develop the SVM classifier. The objects were the endoscopic images in the animal experiments with the approval of the local ethics committee for animal experiments using four specific pathogen-free (SFP) pigs that weighed approximately 30 [kg]. Laparoscopic non-ischemic partial nephrectomy [101] was performed using the WaFLES technique by two urologists. The non-ischemic partial nephrectomy does not cause ischemia; therefore, although damage to the normal tissue is suppressed [101], hemostasis is important because bleeding is frequent. From the obtained endoscopic images, the organ region pixels (206606 pixels), bleeding region pixels (147456 pixels), and hemostasis region pixels (147456 pixels), a total of 501518 pixels, were randomly extracted (Fig. 4.2). The organ region showed various color characteristics; therefore, more samples were obtained for it than other regions.

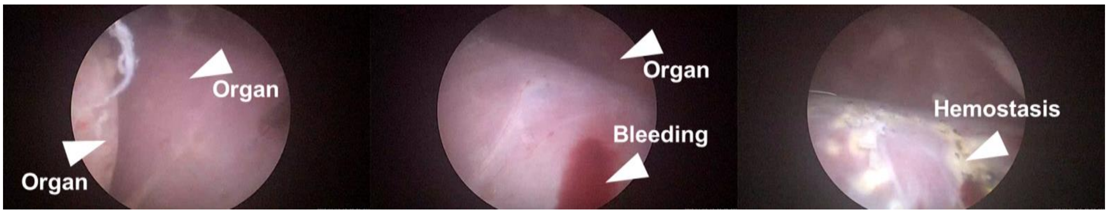


Fig. 4.2 Regions (white triangles) obtained from the endoscopic videos through the WaFLES technique.

The linear SVM classifier was trained by our training dataset and verified by the stratified five-part cross-validation. In this verification, the true positive (*TP*), true negative (*TN*), false positive (*FP*), and false negative (*FN*) rates were obtained from the rate of the pixels classified in each region.

By comparing the SVM classifier using our descriptors with the conventional descriptors, more robust classification was guaranteed.

・Analysis of the termination condition of hemostasis

We performed the time-series analysis of hemostasis to obtain the termination condition. The objects were the endoscopic images of the bleeding and hemostasis regions in the four animal experiments, and ten hemostasis procedures were extracted. For the endoscopic images of hemostasis, the region of interest (400×400 pixels) was manually defined. In one hemostasis procedure, five endoscopic images were extracted from the endoscopic videos, from the bleeding to hemostasis procedure, because the endoscope image was not fixed. Endoscopic images from the same viewpoint were suitable for our analysis. Fig.4.3 shows the endoscopic images of the ten hemostatic techniques targeted in this study. Moreover, these procedures were confirmed by the urologist as complete hemostasis.

Fig. 4.3 Ten hemostasis procedures targeted in this study (Label of time series from 1 to 5), (Procedure 1, 2, 3, 4 and 5).

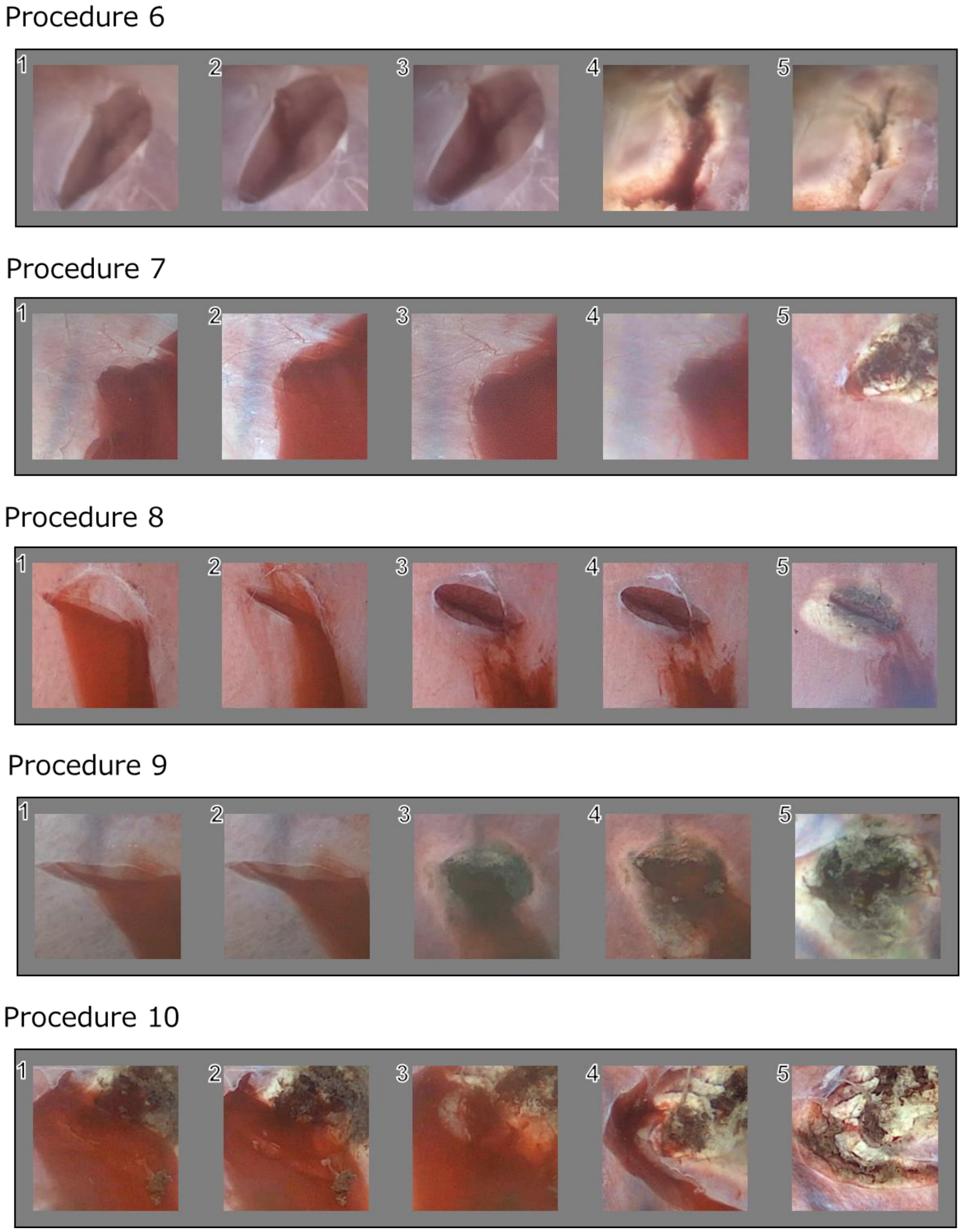


Fig. 4.3 Ten hemostasis procedures targeted in this study (Label of time series from 1 to 5), (Procedure 6, 7, 8, 9 and 10).

According to the mechanism of the hemostasis procedure, we first observed a large area of bleeding, and believed that the hemostasis area increased as the hemostasis progressed. Therefore, to visualize and quantify the state transition of the hemostasis procedure, the rate of the bleeding region sizes, and the hemostasis region sizes were calculated:

$$S_c = S_b / S_h \ ,$$
$$if\ S_h = 0, \quad S_c = S_b \ , \tag{4.1}$$

where S_b is the bleeding region sizes, S_h is the hemostasis region sizes, and S_c is the rate of the bleeding and hemostasis region sizes.

4.3 Results

The stratified five-part cross-validation for the linear SVM classifier using our descriptors revealed that the classification accuracy was 96.7%, which was better than that obtained using the conventional descriptors (92.1%). Fig.4.4 shows the confusion matrices and the *TP* and *FN* rates of each region in the classifier using the proposed and conventional descriptors.

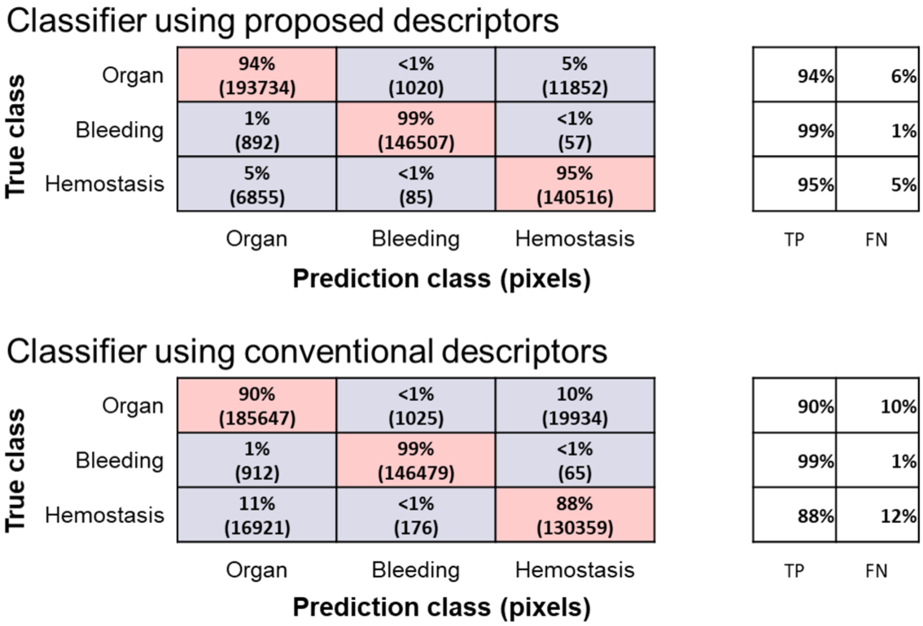
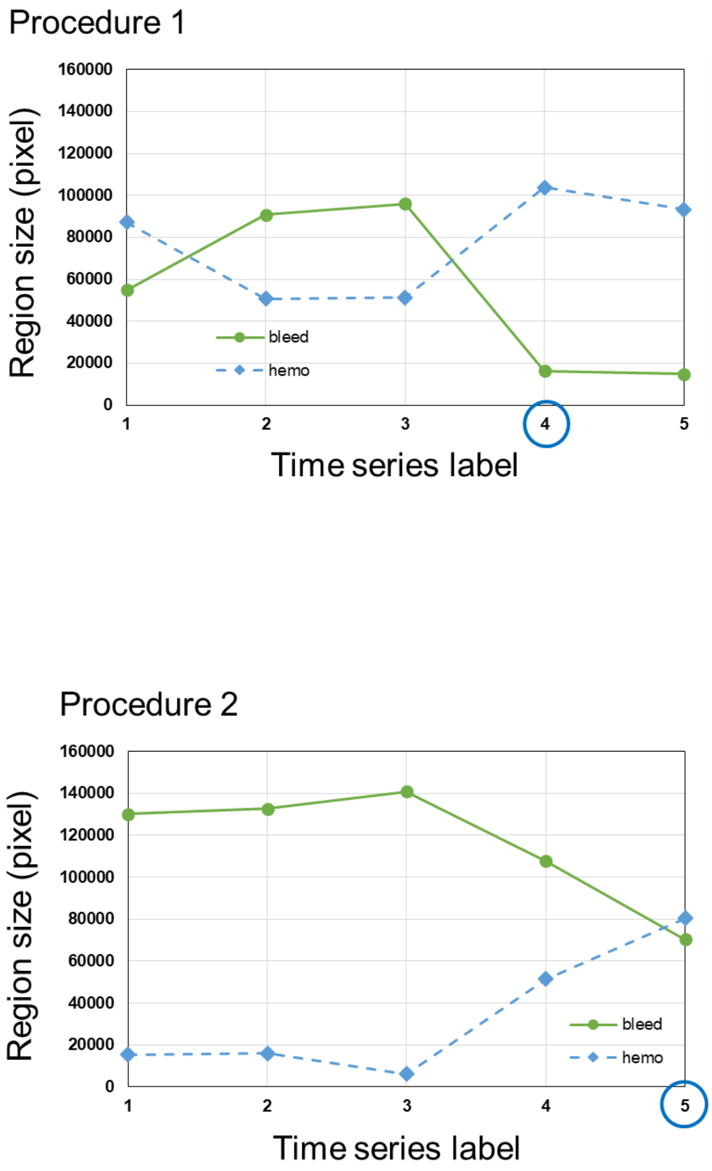


Fig. 4.4 Confusion matrices and true positive (TP) and false negative (FN) rates in each region.

For the termination condition analysis, the change in the size of the bleeding and hemostasis regions in the hemostasis procedure in a time series labeled 0 to 5 is shown in Fig.4.5. In addition, the labels that were confirmed to be hemostasis labels by the urologist were indicated using blue circles.



○ **: Endpoint of hemostasis procedure according to urologist**

Fig. 4.5 Change in the size of the bleeding and hemostasis regions (Procedure 1 and 2).

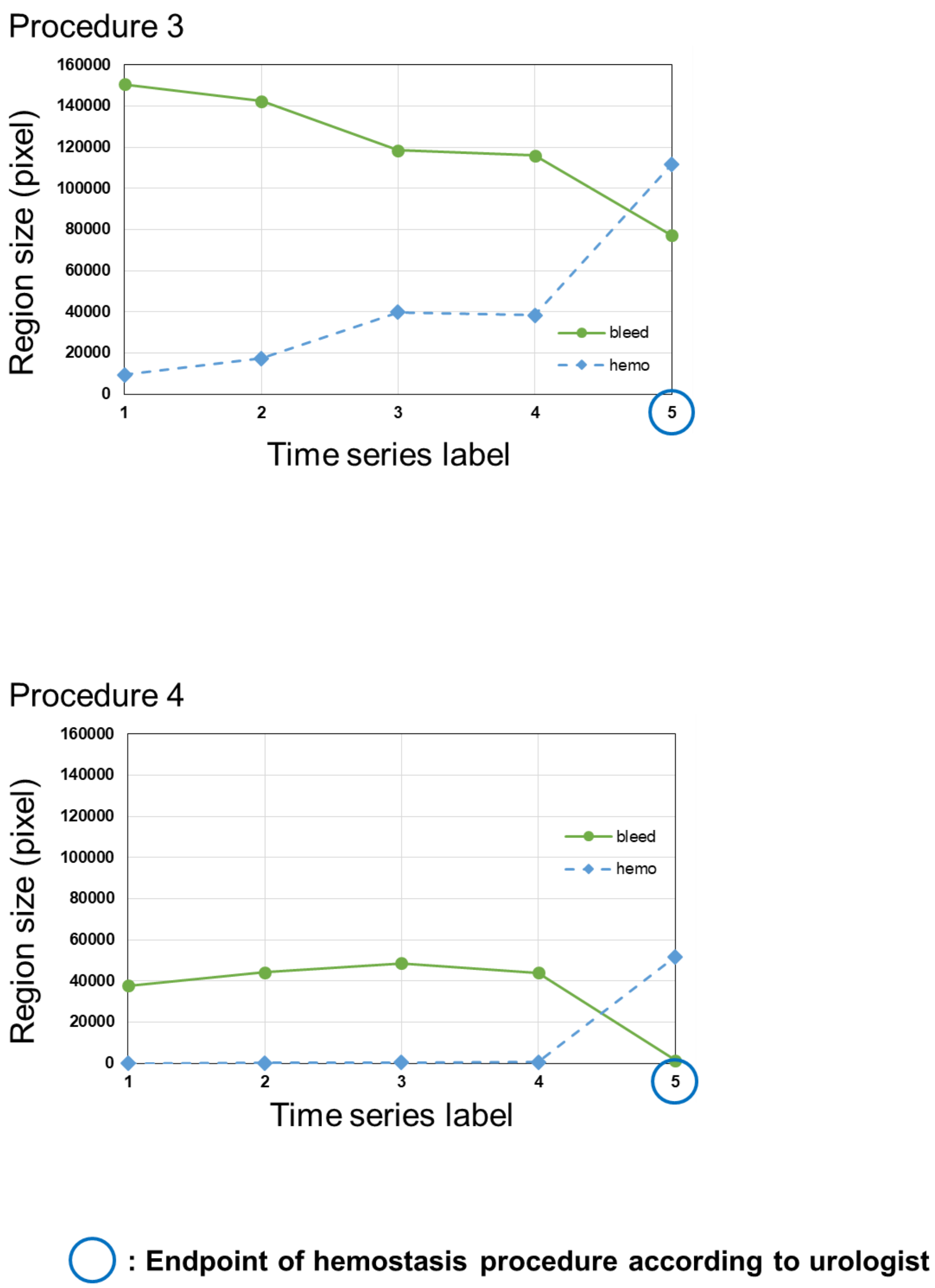


Fig. 4.5 Change in the size of the bleeding and hemostasis regions

(Procedure 3 and 4).

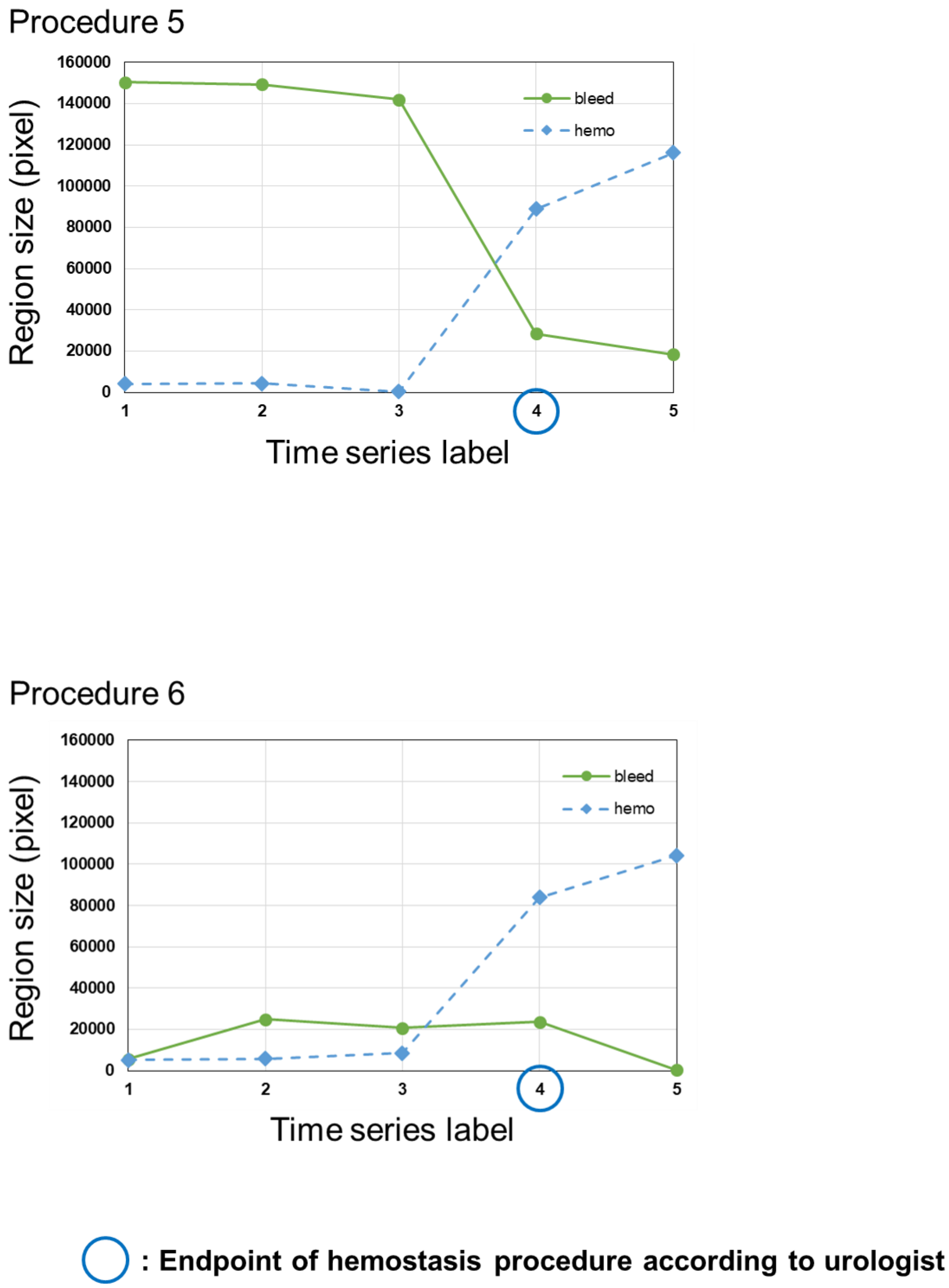
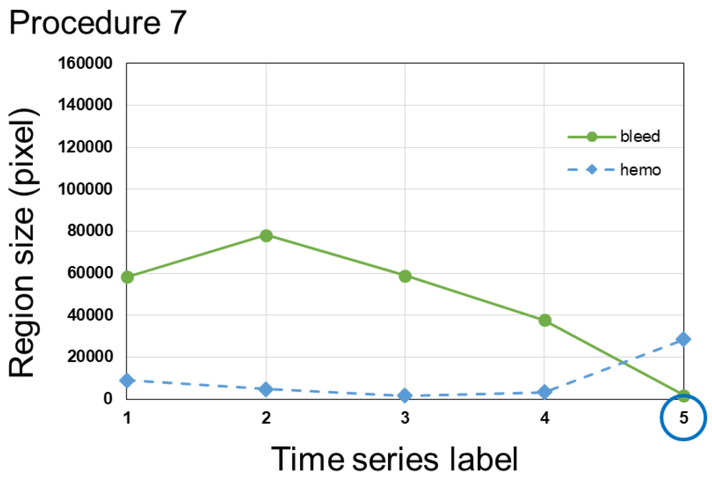
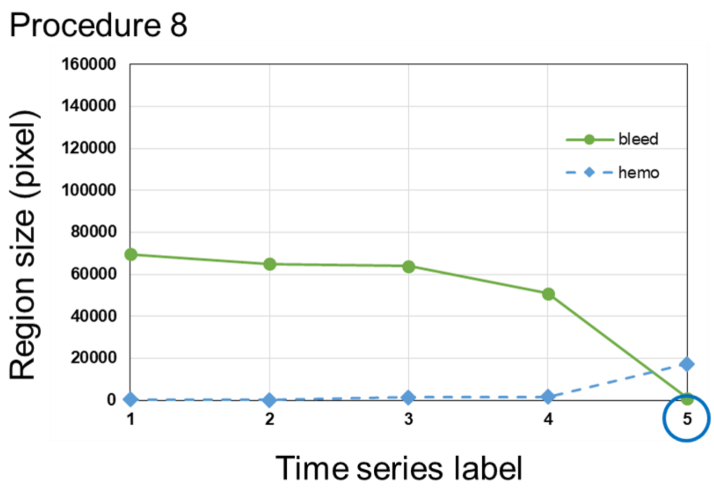


Fig. 4.5 Change in the size of the bleeding and hemostasis regions

(Procedure 5 and 6).

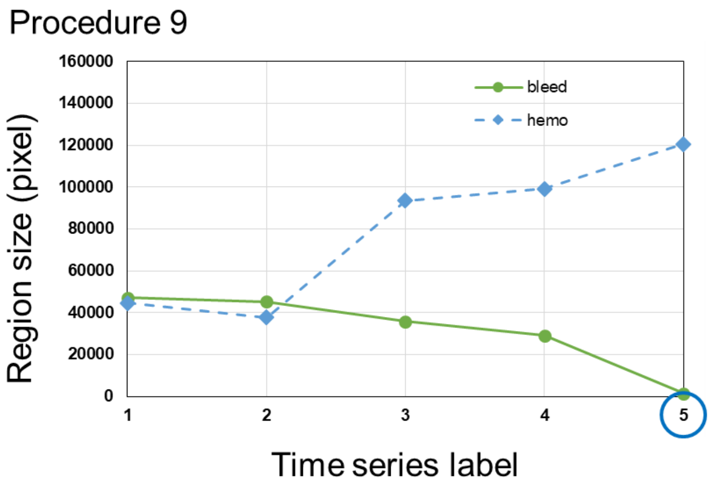


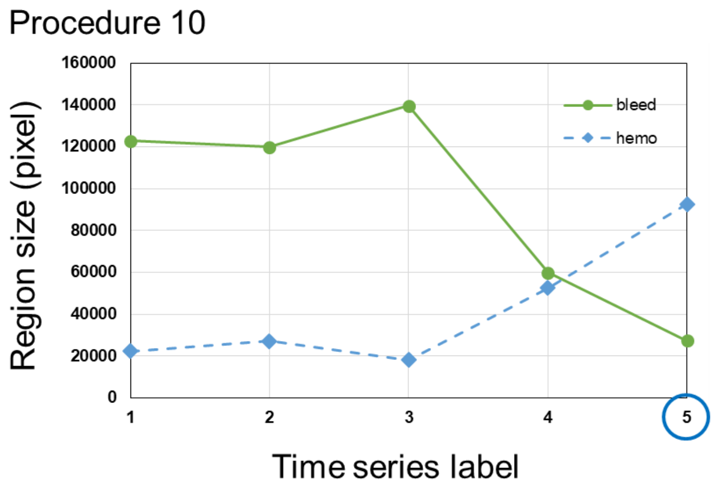


: Endpoint of hemostasis procedure according to urologist

Fig. 4.5 Change in the size of the bleeding and hemostasis regions

(Procedure 7 and 8).





○ **: Endpoint of hemostasis procedure according to urologist**

Fig. 4.5 Change in the size of the bleeding and hemostasis regions

(Procedure 9 and 10).

Furthermore, Fig.4.6 shows the change in the rate of the bleeding and hemostasis region sizes obtained using Equation (7). In the figure, the vertical axis uses the common logarithm display.

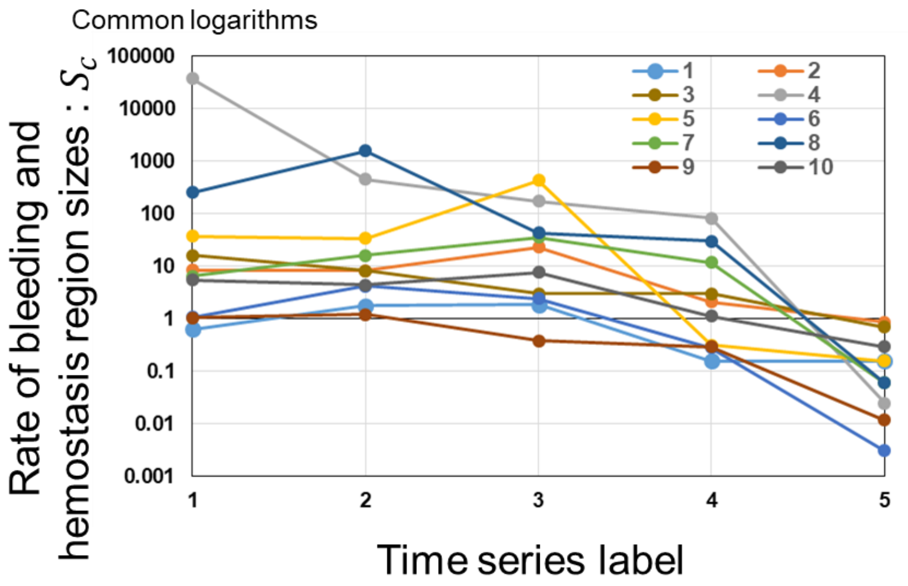


Fig. 4.6 Change in the rate of bleeding and hemostasis region sizes.

Moreover, we compared the S_c of the label before the endpoint and that at the endpoint of the hemostasis procedure in Fig.4.7 and obtained $p << 0.01$ using the Mann–Whitney U-test.

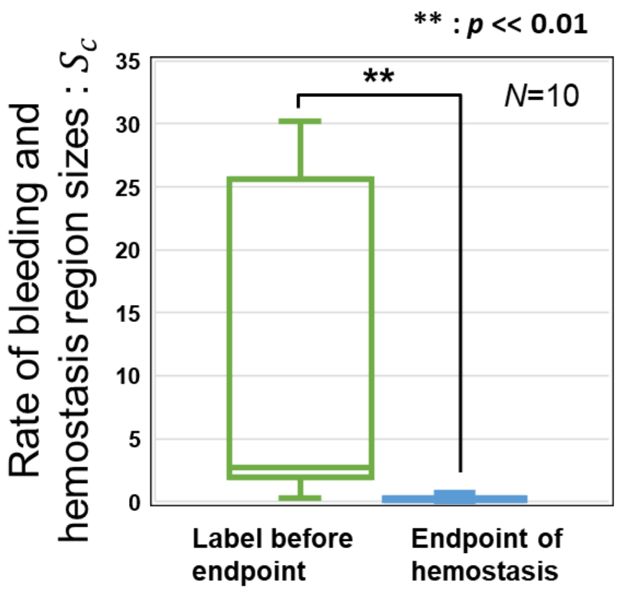


Fig. 4.7 Comparison of the Sc which were the label before endo point and endpoint of hemostasis.

4.4 Discussion

・Detection using proposed descriptors based on an extended dataset

We extended the dataset to enable a more robust detection of the organ, bleeding, and hemostasis regions. The results of the stratified five-part cross-validation showed that the proposed color feature descriptor was more robust than the conventional color feature descriptor. The results of Fig.4.4 showed that our SVM classifier was able to reduce misclassification of organ and hemostasis regions compared to the conventional SVM classifier; thus, we obtained satisfactory results with high *TP* and low *FN* values.

In our system, the lighting environment, the color of the organ, and the white balance of the complementary-metal-oxide–semiconductor camera were considered to affect the detection accuracy, because our SVM classifier used color information of the endoscopic images. Establishing a dataset with more cases helped improve the robustness of the SVM classifier. We also demonstrated that the proposed robust detection technique was effective when applied to various hemostasis procedures, thereby indicating the versatility of the method.

・**Analysis of hemostatic procedures**

The urologist confirmed that for all ten procedures shown in Fig.4.3, hemostasis conducted using an energy device from the state when bleeding occurred was complete. Moreover, as shown in Fig.4.5, we were able to visualize the transition between the bleeding and hemostasis regions using the proposed detection method. Many hemostasis procedures initially detected a large bleeding region. The size of the bleeding region detected in Procedure 6 was smaller than that in other procedures because Procedure 6 was a case in which the amount of bleeding was very small. Furthermore, as the procedure progressed, there was a tendency for a larger hemostasis region to be detected. The hemostasis procedure in the WaFLES technique involved coagulation using the energy device and blood washing. In addition, this procedure could suppress bleeding rapidly after a certain period owing to the applied water pressure [71,72]. This effect was one of the advantages of the WaFLES technique.

In Fig.4.5, it could be observed that the size of the hemostasis region was larger than the size of the bleeding region. Many procedures suggested that hemostasis was complete when the hemostasis region was the larger than the bleeding region. In Procedure 9, even when the hemostasis region was larger than the bleeding region, hemostasis did not immediately come to an end, because in this procedure, the bleeding point could not be efficiently coagulated by the energy device. If coagulation cannot be performed efficiently, the hemostasis region will increase but the bleeding will not stop; thus, it is considered important to coagulate the bleeding point properly. The results also suggest that our system could perform the hemostasis procedures efficiently and that it could be used during surgery.

・**Termination condition of hemostasis procedures**

The method proposed using Equation 4.1 adopted an algorithm with a low computational cost as the final goal of our study was to assist and automate the hemostasis procedure based on a real-time analysis. The results showed that monitoring the hemostatic procedure using the proposed method based on Equation 4.1 was effective in providing assisting and enabling automation of the hemostasis procedure. The results of Fig. 6 showed that the rate (S_c) of the bleeding and hemostasis regions tended to converge to 1 or less, because as the hemostasis procedure progresses, the size of the bleeding region decreases, and the size of the hemostasis region increases. Additionally, according to Fig.4.7, it was considered that by using our method, sufficient hemostasis could be achieved when the rate (S_c) of the bleeding and hemostasis regions was ≤1. In Fig.4.7, the S_c value in the endoscopic images confirmed to be done hemostasis by the urologist and the S_c value in the endoscopic images of the immediately preceding state were compared. The Mann–Whitney U-test results confirmed a significant difference with a high value of the dominant level of 1% or less. These results confirmed that calculating the rate of the bleeding and hemostasis region sizes and using it as a threshold for the termination condition can be effective in automating the hemostasis procedures. In this study, hemostasis was considered complete when the S_c value ≤ 1; however, as the absolute value may vary, it was necessary to carry out further verification experiments. The hemostasis procedure was not completed for a while even if the S_c value became 1 or less in Procedure 9. As described in the Section 4.2, Procedure 9 was a case in which effective hemostasis could not be performed; therefore, it was considered necessary to add another condition if the decrease in the bleeding region was small regardless of the increase in the hemostasis region.

Moreover, although it was judged that hemostasis was complete when the S_c value ≤ 1 in Procedures 2 and 3, the detected bleeding region was larger than those observed in other procedures. The reason for this may be false detection of the bleeding region and small amounts of remaining bleeding. The erroneous detection needed to be corrected by expanding the dataset. The surgeons finished the hemostasis procedure because the remaining small bleedings were expected to stop naturally over time. A continued hemostasis procedure increased coagulation, which caused inflammation and damaged normal tissues [99, 102]; this was undesirable from an invasive point of view.

In other words, even if the S_c value was sufficiently small, caution was still required when the bleeding region was still large; the size of the bleeding region was a part of the termination condition of the hemostasis procedure. In this regard, we considered that further verification experiments were necessary.

・Limitations of the current study

In this study, we determined the termination condition of hemostasis procedures based on the detected and measured bleeding and hemostasis regions and aimed at providing assistance for and enabling the automation of such procedures. During detection, a region of interest was defined, and an analysis was performed for a procedure in which there was one bleeding region. Therefore, we considered that there were limitations when multiple bleeding regions occurred. However, when multiple bleeding regions occurred, it was thought that the amount of bleeding would be very large, and in this case, it was highly likely that a direct manual hemostasis procedure by a surgeon would be required. It was considered necessary to select a target bleeding region even when the proposed system was used to assist and automate the hemostasis procedure.

Furthermore, because it was necessary to coagulate the bleeding point efficiently, a surgical robot that tracked moving organs by pulsation could be integrated with the proposed system. Methods using a three-dimensional position measurement device as well as methods using the optical flow [95] calculated from feature points on endoscopic images have been studied as tracking methods. Therefore, our future research will focus on the development of an organ-tracking hemostasis support robot system incorporating the proposed detection method and termination conditions of the procedure.

4.5 Brief Summary

We conducted a time-series analysis of the endoscopic images obtained during hemostasis procedures and examined some of the procedure termination conditions required to develop a robot system that can enable automation and provide assistance. The organ, bleeding, and hemostasis regions were detected from the endoscopic images using a linear SVM based on an extended dataset. Our SVM classifier was more robust as shown by a comparison of conventional feature descriptors and the proposed feature descriptor. Moreover, an analysis of ten hemostasis procedures suggested that the proportion of the bleeding and hemostasis regions could be used as part of the termination condition of hemostasis procedures. In addition, an analysis of the hemostasis procedure could contribute to its automation and an increase in its efficiency. Further research will be conducted to integrate the proposed detection method to surgical robots.

Chapter 5　Conclusion

In this study, we developed the device aiming to establish a WaFLES technique that can maintain and improve the QoL compared with the conventional endoscopic surgery and reduce the burden on the patient during the surgery. Furthermore, advanced surgical treatment tends to require the doctors with advanced skills, and the burden on doctors is increasing. Therefore, compared to the conventional endoscopic surgery, the WaFLES technique facilitates continuous observation of the bleeding points due to the stable washing effect. Therefore, the hemostatic procedure is detected from the bleeding, and the hemostatic procedure is assisted and automated. We developed the elemental technology for the assisted and automated of the hemostatic procedure.

In the device development aimed at establishing the WaFLES technique, the cistern [69] was installed outside the body cavity to realize a perfusion environment with the single incision as the inflow surface, and compared to the conventional WaFLES technique, the safer WaFLES technique in the liquid was achieved. As the results, the continuous bleeding could be observed and the clear endoscopic images could be acquired, which not only reduces the intraoperative burden on the patient and maintains and improves QoL, but also develops the technique that reduces the burden on the doctor.

Following the development of the extracorporeal cistern [69] that established the WaFLES technique, the aim of assisting and automating the hemostasis procedure by utilizing the advantages of the WaFLES technique, such as the acquisition of the clear endoscopic images and the continuous observation of the bleeding. The burden on the doctor during the surgery is increasing. We conducted technical development to reduce the burden on the doctor during the surgery enable safer and more precise procedures. Due to the characteristics of the hemostasis procedure, it was required to detect three regions in real-time: the organ, bleeding, and hemostasis region. Therefore, we have implemented real-time detection by the linear SVM. As the results, we demonstrated the usefulness of our method [100] by achieving the enough accuracy for the region detection and the computational cost that can be processed intraoperatively. In addition, we analyzed changes in the color characteristics based on the tissue coagulation due to the bleeding and the protein degeneration due to energy devices in the hemostatic procedure using the proposed region detection method. Based on these results, we proposed an index that can contribute to the determination of the end of the hemostatic procedures using the energy device and demonstrated its usefulness. Then, it was considered that the development of a part of the elemental technology for assisting and automating hemostatic procedures was successful [103]. It was expected that the surgical robot incorporating these technologies and the real-time surgical navigation would greatly reduce the burden on the doctor and contribute to solving social problems in the medical care.

In this study, the burden on the patient was reduced by the establishing the WaFLES technique by the extracorporeal cistern development, and the increasing intraoperative burden on the doctor was made possible by the medical image processing and medical information processing technology, and the burden on both the doctor and the patient was reduced. We would like to connect to the medical assistant and automatic technology for the surgical treatment.

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Research achievements

A. Original papers

1. Matsunaga Y, Nakamura R, Analysis of Hemostasis Procedures through Machine Learning of Endoscopic Images towards Automatic Surgery, Sensors and Materials, MYU Tokyo, 2020;32(3):947–958, 03/2020.

2. Matsunaga Y, Nakamura R, Development of detection method for automatic hemostasis using machine learning with abdominal cavity irrigation, International Surgery Journal, 2020;7(7):2103-2109, 07/2020.

B. Reference papers (original papers not related to this paper)

1. Teranaka S, Ishii T, Matsunaga Y, Koyama A, Kahara K, Ssakamoto S, Ichikawa T, Igarashi T, Skeletonization of Renal Cysts of Autosomal Dominant Polycystic Kidney Disease using Magnetic Resonance Imaging, Journal of Medical Imaging and Health Informatics, Journal of Medical Imaging and Health Informatics 2017;7:568-573, 06/2017.

2. Matsunaga Y, Ishii T, Igarashi T, Three-Dimensional Skeletonization Algorithm for Morphological Analysis of Renal Cysts in Patients with Autosomal Dominant Polycystic Kidney Disease, Medical Imaging Technology, 2018;36(5):231-237, 12/2018.

C. Conference presentation

1. Matsunaga Y, Igarashi T, Nakamura R, Bleeding and Hemostasis Region Extraction using a Support Vector Machine for Automatic Hemostasis Surgery with Abdominal Cavity Irrigation, 33nd International Congress on Computer Assisted Radiology and Surgery (CARS2019), Rennes, France, 06/2019.

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3. 松永 佳久，五十嵐 辰男，中村 亮一，等張液灌流式腹腔鏡下手術における体腔外設置型水槽の開発，第 26 回日本コンピュータ外科学 会大会，名古屋，10/2017.

4. 松永 佳久，石井 琢郎，中村 亮一，五十嵐 辰男，人工腹水灌流下ミニマム創内視鏡下手術における体腔外設置型水槽の開発，第 30 回日 本内視鏡外科学会総会，京都，12/2017.

5. 松永 佳久，五十嵐 辰男，中村 亮一，小切開創手術における効率的な術野確保に向けた形状記憶型開創器の開発，第 31 回日本内視鏡外科学会総会，福岡，日本内視鏡外科学会雑誌，23(7):OS34-1，12/2018.

D. Patent

1. Matsunaga Y, Ishii T, Igarashi T, Operation field-securing device, Patent number: 10314569(USPTO), 06/2019.

2. 公開番号 2018-086168, 特許第 6622175 号「トロッカー」, 大矢 朋代, 松永 佳久, 五十嵐 辰男, 関根 雅, 石井 琢郎, 11/2019.

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E. Reference patent (patent not related to this paper)

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F. Award

1. 松永 佳久, 研究奨励金, 第 25 回嚢胞性腎疾患研究会, 10/2017.

2. 松永 佳久, なのはなコンペ 2018, なのは賞(正賞), 04/2018.

3. 松永 佳久, なのはなコンペ 2018, 日本インサイトテクノロジー賞(特別賞), 04/2018.

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