Clinical Trial of Information Acquisition System for Surgical Instruments in Digital Operation Room

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Abstract. To prevent incidents in which surgical items are retained in a patient's body, a unique device system (UDS) of surgical instruments in the operation room is required. In our previous study, we developed surgical instruments with radio-frequency identification (RFID) tags and a UDS antenna to assign unique identification to each instrument in operation room. The purposes of the present study were to evaluate the recognition accuracy of the antenna system during surgery and determine the usage rate of preoperatively prepared surgical instruments. The experiments were conducted in four inguinal hernia surgeries. The recognition accuracy of data acquisition was 97.7%. The one cause that decreased this rate by 2.3% was occasional placement of the RFID tags outside the radio communication range of the antenna. However, when the surgical instruments were moved by a nurse and returned to the antenna, the system could detect all instruments. The system could detect RFID tags during surgery, and the accuracy was maintained when the scrub nurses placed the instruments on the antenna unconsciously. The total usage rate of the preoperatively prepared surgical instruments was 50.0%. Thus, half of the surgical instruments were not used during surgery and underwent a repeated sterilization and washing process. These instruments are exposed to high pressure and temperature, increasing the risk of instrument defects. The system described herein can clarify these rates and help to optimize the number of surgical instruments that are prepared before surgery.

Keywords: RFID tags · Surgical instrument · Antenna

1 Background

Surgical items are retained in a patient's body once in every 10,000 operations, and 30% of the items are surgical instruments [1, 2]. This problem is caused by complex counts and defects of surgical instruments. First, a nurse conducts a surgical count, and the medical staff repeatedly counts all sponges and instruments in the perioperative period. The scrub nurse who passes the instruments to the surgeons must also

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simultaneously conduct surgical counts and provide support during the surgery. The surgical count depends heavily on a manual count method, which has a risk of miscounting. The World Health Organization reported that manual counting is not foolproof [1] and that support by a counting system is required. Second, because the surgical instruments are not managed individually, the causes of surgical instrument defects are not always clear. To prevent these issues, a unique device system (UDS) that can recognize each instrument individually in the operation room (OR) is required.

In a general hospital, a surgical instrument set is assembled before surgery to streamline preparation of the OR. A set consists of multiple types and numbers of instruments, and the total number of instruments is 10 to 200. The lists of instruments are fixed for each surgical type in each hospital. However, the list of surgical instruments that are prepared before surgery is not optimized; instead, the instruments are compiled at the surgeon's discretion. Un-optimized sets lead to an overloaded washing and sterilization process for surgical instruments. Too many instruments in the set will lead to a complicated surgical count for medical staff in OR and potentially impact risks of miscounts.

In our previous study, we developed surgical instruments with radio-frequency identification (RFID) tags (Fig. 1) and software to recognize each instrument in the OR [3]. Each RFID tag has a unique ID (UID) for easy identification, and each instrument can be recognized automatically. The tag is covered by ceramic and can tolerate the processes of washing and sterilization in the hospital. An antenna system was also developed in that study. The system detects the RFID tag and obtains a UID when nurses place the surgical instruments on the antenna plate. The system allows for recording of the number of uses and defect history of each instrument. The frequently used data of instruments being transferred from one set to another are recorded. The results of that study suggest that this system can trace each instrument [4].

The purposes of the present study were to evaluate the recognition accuracy of the antenna system during surgery and determine the usage rate of surgical instruments that were prepared before surgery. Finally, we discuss the possibility of applying our system to a workflow model and digital OR.

Fig. 1. Surgical instrument with RFID tag [3]

2 Methods

Our system was placed on a Mayo table, which is an instrument table positioned over the patient, and the table was then covered by a sterilized surgical drape. As the RFID surgical instruments are placed on the table (Fig. 2), the system can automatically detect these tags and obtain a UID. To obtain the correct number of instruments in the present study, the instruments were visually counted using a video camera at the same time as control data. The accuracy of the system was calculated by the following formula (1):

$$\mathit{Accuracy\ of\ system}\,[\%] = Sn/Vn \times 100 \tag{1}$$

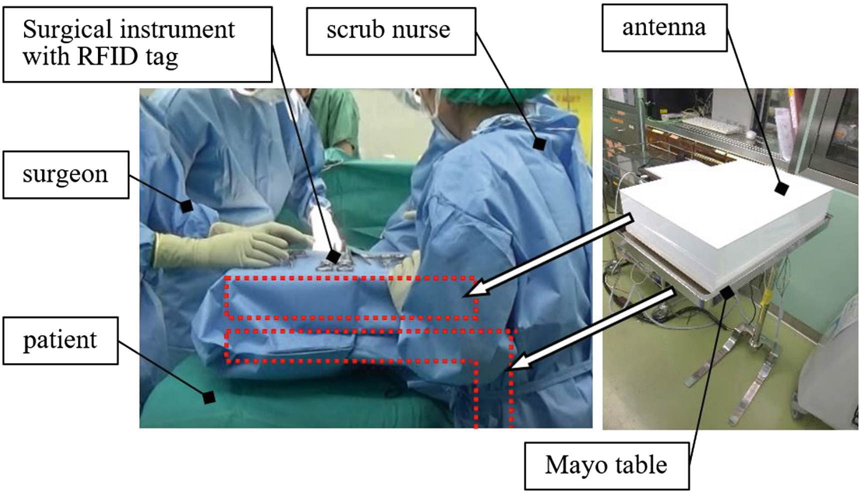

Fig. 2. Antenna system on Mayo table, covered with a sterilized surgical drape

Vn: total number of instruments counted using video camera

Sn: total number of instruments counted using system

To obtain a gold standard number, the experiments were conducted in four inguinal hernia surgeries. Sixty-one surgical instruments of 20 types with RFID tags were prepared for hernia surgery. Fifty-seven surgical instruments of 18 types were used for calculation of the accuracy because 3 towel forceps and 1 knife holder were not used on the instrument table in these surgical cases. The usage rate of the instruments was calculated by the following formula (2):

$$\mathit{Usage\ rate}\,[\%] = Un/In \times 100 \tag{2}$$

Un: number of instruments placed on the antenna

In: number of instruments in a hernia set

3 Results

Figure 3 shows the number of surgical instruments that were placed on the Mayo table during surgery. The number of instruments placed on the antenna plate at the same time ranged from 1 to 10 in this case. The data of the four hernia surgeries are shown in Table 1; the total average accuracy of data acquisition was 97.7%. Because the RFID tags were sometimes placed outside the radio communication range on the antenna, they could not always be detected. However, when the surgical instruments were moved by a nurse and returned to the Mayo table, the system could detect all instruments.

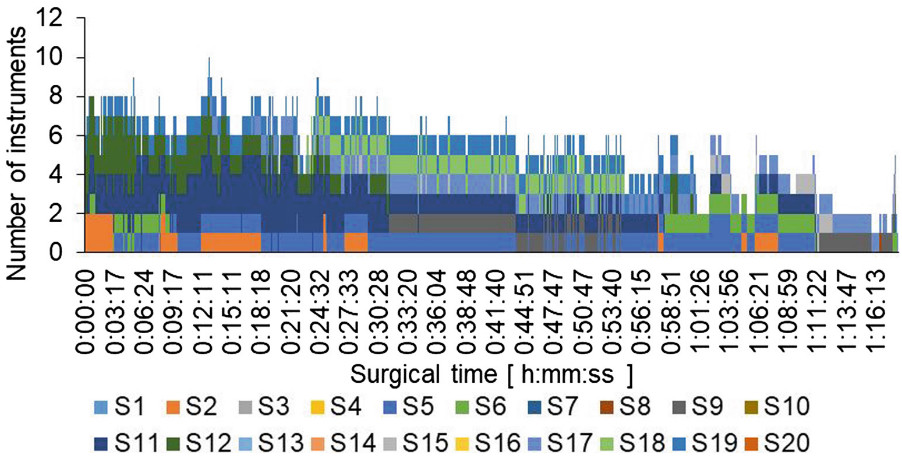

Fig. 3. Count number of each type of instrument using the RFID system

Table 1. Results of clinical trial of the system

#	Surgical time [minutes]	System accuracy [%]	Usage rate of instruments [%]
1	79	96.8	50.9
2	60	99.4	43.9
3	67	97.1	49.1
4	78	97.7	56.1

The total usage rate of the surgical instruments in the surgical sets was 50.0%. Nevertheless, the sets contained 57 surgical instruments including 18 types. 10 Halsted mosquito forceps were included in the set; however, the usage rate was around 22%. Additionally, some instrument types were not used during surgery.

4 Discussion

4.1 Recognition Accuracy of Surgical Instruments Using the UDS

Several previous studies have been performed in an attempt to detect surgical instruments separately by image processing or barcodes [5, 6]. However, these methods fail to detect some instruments because of overlap and the presence of blood. To recognize barcodes, nurses must scan it one by one and wipe blood from the surface of the instrument. This operation leads to human error and is not adequate for use in OR. In the present study, the RFID tags communicated by radio-frequency, and the system could detect instruments that overlapped and contained blood.

As an RFID mechanism, tags can send and receive information when the tags and antenna are set in parallel. Scrub nurses place instruments on the table unconsciously, and RFID tags become perpendicular to the plane of the instrument table. Therefore, the magnetic flux from the system cannot pass the tag. This technical issue should be resolved to acquire data of surgical instruments in the OR.

In general, the antenna structure is a single-loop antenna, and the magnetic flux is uneven on the antenna plate. Therfore, a reader can detect the UID of instruments when the RFID and antenna are only in parallel. The system that was developed in our previous study used multiple antennas, resulting in multi-magnetic flux. In the present antenna, the magnetic flux becomes smooth (Fig. 4) [7]. The system maintains an adequate communication distance and detects RFID tags during surgery, and the accuracy remains high when the scrub nurses set the instruments down unconsciously.

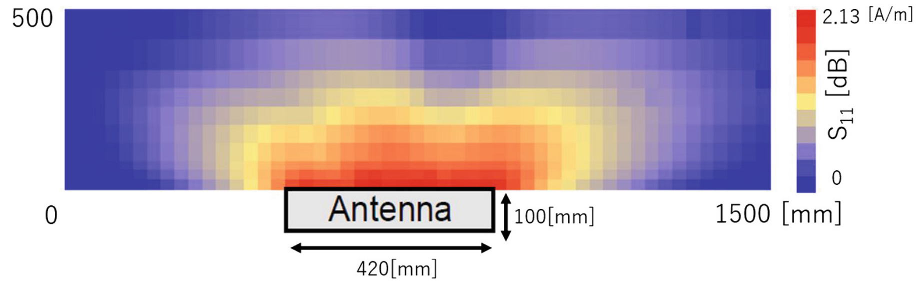

Fig. 4. Magnetic flux using antenna of UDS [7]

4.2 Usage Ratio of Surgical Instruments in a Set

In each hospital, surgical sets of sterilized instruments are prepared preoperatively for specific types of procedures. There is no established list of instruments to include, and medical staff make independent judgments about decreasing or increasing the number of instruments. In fact, most surgical sets contain more than the required number of instruments. However, defects of instruments have been reported despite the fact that the instruments were not used during surgery. The inclusion of the extra instruments in the surgical set is associated with defect formation.

In this study, the rate of surgical instrument use in each set was 50%. Most of the surgical instruments in the sets were not used during surgery, and the washing and sterilizing processes were repeated. To prevent defects of instrument, the number of surgical instruments must be minimized. However, because each set includes extra instruments for emergency situations, unused instruments cannot simply be removed from the set. Continuing clinical trials will clarify the optimal number of instruments.

The period and frequency of instrument breakdowns can be approximated by a bathtub curve. Medical equipment (e.g., syringe pumps, electric knives) are maintained routinely and managed individually. The period and frequency of breakdowns cannot be estimated for surgical instruments because these instruments are not individually managed [8]. Therefore, instrument defects unexpectedly occur during surgery. Our UDS provides new insight into the defect rate of surgical instruments as determined by the management method.

4.3 Digitalization of Workflow and Medical Device Data

Several previous studies involved digitalization of the surgical scenario to develop a scrub nurse robot and optimize workflow. Motion of medical staff was detected automatically during laparoscopic surgery, and the workflow was analyzed [9]. Image processing and an RFID system were used, and the system detected phases automatically [10].

In this study, each surgical instrument was detected automatically, and the UID of instruments and date of detection were obtained. Additionally, we are developing a Smart Cyber Operating Theater (SCOT) as part of our project. This system connects medical devices that are made by various companies using OPeLiNK [11]. Connecting our system with OPeLiNK will allow for detection of surgical instruments and digitalization of surgical items.

4.4 Limitation of This Study

A limitation of this study is that some surgical instrument skipped Mayo table could not detect. Usually, two surgical tables are used in a surgery. Often used instruments are placed on Mayo table, and unused instruments at the surgical phase are placed on another instruments table. For example, a knife holder was usually skipped Mayo table to prevent cutting unconsciously, so it omitted from the calculations in this study. Our study is developing new antenna for surgical table. The system will be developed, and surgical instruments can be counted automatically.

Additionally, the described system cannot be used to attach an RFID tag to certain instruments, such as the small clips used for brain surgery or a strip retractor that bends at the point of RFID tag attachment. These instruments still need to be counted manually. Miniaturization of RFID tags or coexistence of the tags with another detection system may help to realize total management of instruments.

5 Conclusion

Incidents in which surgical instruments are retained in a patient's body occur even today, and the causes are miscounting and defective surgical instruments. The final goal of this study was to establish a surgical instrument management protocol for use in the OR. Such an individual management system was developed in this study, and a clinical trial was conducted to evaluate the accuracy of recognition of RFID tags and determine the usage rate of surgical instruments. The total accuracy of data acquisition was 97.7%, and the total usage rate of the instruments in surgical sets was around 50.0%. Our system can automatically detect these tags and obtain information during surgery; these data can then be utilized when devising instrument sets.

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