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Validation of Cleaning Evaluation of Surgical Instruments with RFID Tags Attached Based on Cleaning Appraisal Judgment Guidelines

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Abstract— **In medical institutions, the threat of infection is closely focused, in particular, inspections regarding surgical site infections (SSI) are carried out. In this study, development of the application of Radio frequency identification (RFID) tags for surgical instrument has been promoted. It enables traceability and individual management of surgical instruments. An experiment was carried out following the cleaning Appraisal guidelines, which contaminated surgical instruments, and using the washer-disinfector (WD) as the main cleaner for surgical instruments with developed RFID tags attached to them. As a result, all of the instruments with RFID tags, the amount of residual protein was less than the recommended acceptable level of 100μg. If WD is used correctly, a sufficient cleaning effect can be expected. From this result, it became evident that the secondary infection risk is low from surgical instrument with RFID tags attached**

I. Introduction

In medical institutions, the threat of infection is closely focused, in particular, inspections regarding surgical site infections (SSI) are carried out[1,2]. For prevention of SSI, the 3 things considered the most important are measures to prevent infection during and after surgery, and management of medical devices used in surgery. This study focuses on surgical instruments, and in the central sterilization room as the department which conducts washing and sterilization requires the proper management of surgical instruments and recording procedure.

Regarding adverse events that occur in medical institutions, Gawande et al reported that in hospitals in Colorado and Utah, 66% of all adverse events are related to surgery, and of those 54% could have been prevented[3]. Also cases of gauze or surgical instruments being left within the body occurred one time out of every 10,000 operations, and of those, 30% were reported as surgical instruments[4], and the cost of medical fees and damages was large[5,6].

One cause of retained surgical instruments is that mistakes are made placing surgical instruments into containers made differently by operative method, and malfunctioning instruments are mixed in, etc. It has been shown that 50% of central sterilization room incident reports involve mistaken mixing of different surgical instruments, mistaking numbers, insufficient inspection resulting in the mixing of broken instruments[7].

Furthermore, one medical facility has tens of thousands of surgical instruments, however these institutions rarely access how many and what type of surgical instruments they have[8]. It has been shown that the number of institutions who are appropriately managing these instruments, for example, figure out on the number used, is nearly none. It is for that reason that surgeons can empirically understand that there are frequent occurrences of cases of broken surgical instruments[9], and cases of non-detected broken parts of instruments falling into the site of operation or nearby[4].

In order to improve on the background described above, and manage the cleaning and usage history of surgical instruments better, traceability is thought to be essential. If appropriate traceability is applied, a number of times of usage for surgical instruments can be set based on evidence.

In this study, development of the application of RFID tags for surgical instrument has been promoted, as shown in Fig 1. Tests have been conducted of RFID tags and surgical instruments attached to RFID tags and their damage in cleaning and sterilization, as well as tests of load and effects of shock; and those results have been summarized in this study[10,11].

It is thought that the above-mentioned cases of infection related to surgery and residual protein on surgical instruments can be attributed to cleaning inadequacy. Even if it is possible to develop traceability for surgical instruments, cases of infection due to improper cleaning will still have to be avoided. The objective of this paper is that surgical instruments developed with attached RFID tags undergo athorough cleaning evaluation; and this paper goes so far as to address cleaning guidelines. In other words, the possibility of contamination was examined for surgical instruments with attached RFID tags, using a cleaning policy and evaluation

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policy based on a set of cleaning Appraisal guidelines. The secondary infection risks became evident.

Fig.1 surgical instrument attached RFID tag

II. METHOD

A. *Outline of Experiment Based on Cleaning Appraisal Guidelines*

It is recommended that primary cleaning of surgical instruments not be carried out in environments in an operating room. There is a danger of a secondary infection due to inefficiency and injury of medical worker in the operating room, so primary cleaning in the operating room should be avoided, and it is proposed that it should be done in a place like the central treatment room by an experience profession who can conduct a proper cleaning[12,13].

Therefore, completion of cleaning requires time, and it is predicted that secondary infection risk due to inadequate cleaning and the burden to the cleaning department will increase. Thus reducing the burden with use of washer-disinfector (WD) is recommended[13,14], and the index of cleanliness of the contaminated instrument is set to match the instrument post-cleaning. In Japan in the guideline, the allowed amount of residual protein of surgical instruments after cleaning is 0.2 mg per 1 surgical instrument, and the recommended amount is 100μg[15]. In Germany, the limit value is set at 0.2 mg; alarm value at 0.1-0.2 mg; and the acceptable value at 0.1 mg[14]. So it can be said that Germany and Japan have nearly identical cleaning evaluation standards. Therefore, here, an experiment was carried out following the above-listed cleaning Appraisal guidelines, which contaminated surgical instruments using simulated contaminants, and using WD as the main cleaner for surgical instruments with developed RFID tags attached to them.

B. *Method of fixation of Simulated Contaminants*

For the cleaning evaluation, a mock contaminant was made using whole sheep blood treated with heparin and 1% protamine sulfate solution in a 10:1 ratio.

The developed RFID tags were heat-resistant for sterilization in the autoclave, and shock-resistant for dropping and collision. If the cleaning is supposed to be inadequate, it is predicted that inadequately-cleaned blood, etc. will be present on the tag and at the part where the tag is attached.

In a normal usage environment, after usage in surgery, to prevent adhesion of blood, blood coagulation prevention spray and a washing tank are used. It is difficult to think of disposing of an instrument when there are large amounts of blood attached, however when residual protein occur, sterilization by high temperature can sometimes have the effect of hardening the adhesion of blood between the RFID tag and the area of attachment. Here the experiment was framed as the worst-case scenario.

More specifically, on the surface of the RFID tag, 0.025 mL of the contaminant was applied, and after 2 minutes of direct high-temperature treatment. Also on the opposite-side surface of the RFID tag an additional 0.025 mL was applied, and 2 minutes of direct high temperature treatment was conducted. Fig. 2 shows the condition of the RFID tag and area of attachment after the 2 minutes of high-temperature treatment. As can been observed, the contaminant has adhered to the RFID tag and the space between area of attachment.

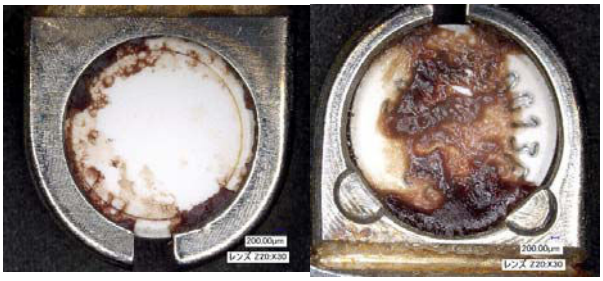

Fig.2 Aspect of RFID tag surface after contaminated

C. *Cleaning Method*

Japan and Germany cleaning Appraisal guidelines have the condition that amounts of residual protein are to be cleaned by WD[13,14]. Therefore this study made cleaning with WD to the cleaning method used. For this experiment, the actual cleaning process was reproduced

The cleaning effects of WD differ depending on their installation position or circumstance of overstuffed surgical instruments. As Fig.2 shows, the worst condition of contamination of the surgical instrument was set, to prove that it could have the highest possible effect. Top-grade WD was applied to contaminated surgical instruments on a cleaning rack. Fig. 3 shows the condition of a WD cleaning basket lined with contaminated surgical instruments. Conducting experiments where it was not mixed with other cleaning agents, the jet spray from WD was found to sufficiently be deployed.

For the reference group, one group was assigned to only undergo an ultrasonic cleaning process. The ultrasonic cleaning used the Sharp MU1100R, with a 15 minute cleaning in 0.5%-adjusted low-foaming alkali detergent (pH:11.4-12.4), and three rinses. To recreate ultrasonic cleaning, the final time, RO water was used. While cleaning, the effect of running water was negated as much as possible to study the effect only of the ultrasonic waves, and no swing was performed.

The non-cleaned group underwent no cleaning process, and surgical instruments were left contaminated with the mock blood.

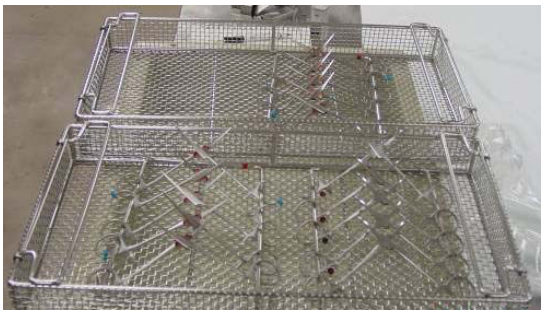

Fig.3 Contaminated surgical instruments were set in washing basket of WD

D. Residual protein amount extraction method and measurement method

The extraction and measurement of residual protein amounts were conducted based on the cleaning Appraisal judgment guidelines[15]. The method is described in detail below. After cleaning, surgical instruments that had received the mock contamination were placed in a polyethylene bag containing 10mL of 0.2mol/L sodium hydroxide. Then they were placed in a circulative thermostat chamber which maintained a temperature of 50 °C centigrade, and while lightly mixing them for two hours, the residual protein was extracted from the instruments. The reason for assigning a two hour time to extra the proteins was that the mock contaminants had strongly adhered to the instruments, so sufficient time for extraction was required.

For detection, the Bradford method (Coomassie brilliant blue:CBB) was used, and 1mL of the extracted liquid and 3mL of the CBB reagent were mixed, and after being left at room temperature for 20 minutes, and the measured wavelength of absorption was 595nm, measured with a spectrophotomer (Shimadzu Co.) . For the protein standard curve, bovine serum albumin was used, and the Coomasie protein assay kit (Thermo Fisher Scientific Co.) was also used. The sodium hydroxide used in the extraction liquid was made by Kanto Chemical Co. The detection limit of the CBB method is 10μg. Therefore if the amount detected is less than 10μg, it will appear as 10μg.

III. Results

Table 1 shows the results of protein amounts given by each parameter of absorption. Fig. 4 shows the frequency distribution of residual protein amounts in the WD group. Fig. 4 shows the extent of the accomplishment of the target goal. Fig. 5 is a picture of an example from the ultrasonic group and one from the WD group after cleaning. In Table 1, the residual protein amount in the WD group had an average of 32.3μg, and the largest amount of residual protein was 96.3μg. The smallest two were below the minimum detection amount of 10μg. The reference, the ultrasonic group, had an average of 1191μg, a maximum of 2605.6μg, and a minimum of 98.0μg. The group that was not cleaned had an average of 5103.1μg, a maximum of 6308.2μg, and a minimum of 4106.9μg.

Table 1 Results of residual protein amount after cleaning

	Residual protain amout [μg]
WD group	32.3±21.9
ultrasonic group	1191.0±1166.8
non cleaning group	5103.1±990.9

mean±SD

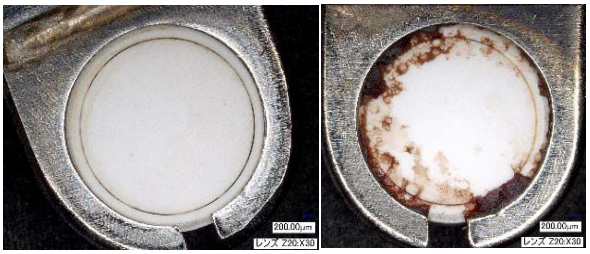

Fig.5 Aspects of RFID tag after cleaning (left: WD group, right: ultrasonic group)

Fig. 4 shows that 8 of the surgical instruments in the WD group, 30.8%, had a residual protein amount less than 20μg, 15 items (57.7%) had 21-50 μg, and 3 items (11.5%) had 51-100 μg. Fig. 5 shows that even after performing a visual check of the surgical instruments with attached RFID tags, on the center-right of the diagram, the residual mock contaminant blood could be seen, however, the contaminants in the WD group on the left could not be seen.

IV. Discussion

This paper, in order to study the effect of developed RFID tags and their areas of attachment on cleaning, evaluated the results according the cleaning Appraisal guidelines set by Germany and Japan. The results show that there were zero cases of more than 0.1 mg, the acceptable value specified in Japanese and German cleaning evaluation judgment, on RFID-attached surgical instruments; showing that a sufficient cleaning was achieved.

The report on WG in the established cleaning Appraisal guidelines of Japan, at medical institutions where tests were carried out, 91 surgical instruments were found by visual inspection to have blood present on them. Cleaning is commonly done with WD, or WD and ultrasonic cleaning, and residual protein amounts are detected using the Bradford method, the same as was done in this experiment. The results showed that those with less than 0.02 mg of residual protein accounted for 53.8%，0.021-0.05mg was 31.9%，0.051-0.1 mg was 6.6%，0.101-0.15 mg was 4.4%，and 0.151-0.2 mg was 3.3%.

These results confirm that the cleaning effect of this experiment and those reported in the Japan cleaning Appraisal guidelines are similar when compared. Furthermore, both surgical instruments that use RFID tags and surgical instruments used in the guidelines had less than the accepted limit of residual protein, 0.2 mg. In fact, in these results all of the surgical instruments with attached RFID tags were less than the target value of 0.1 mg.

The application of the mock contaminant was set to be so bad that it is inconceivable in normal situations. With this condition, the test was conducted. Even with this worst-case cleaning evaluation, the average amount of residual protein stayed below half of the target value, and about 10% was near the acceptable value of 0.051- 0.1 mg. With the condition that proper WD use would be used for the surgical instruments with developed RFID tags attached, this experiment showed that a sufficient cleaning effect was achieved.

The ultrasonic cleaning group tested for comparison did not have a sufficient cleaning effect when only ultrasonic cleaning was conducted. If a medical institution does not have WD, usually some other manual cleaning procedure is used. Also to prevent blood from remaining, coagulation prevention spray, etc. is used, and it is recommended to take the used surgical instruments out of an environment where patients are present to the cleaning department[13,14]. In that way, the worst case scenario used in this experiment is predicted to not happen often.

This mock contaminant experiment showed that blood often remained at the section of RFID attachment and also the box lock of forceps had the same cleaning situation[10]. This secondary infection possibility, not only regarding surgical instruments where RFID tags are attached, needs to examined more closely.

V. Conclusion

This study involved conducting a cleaning evaluation experiment on RFID tag-attached surgical instruments, based on the cleaning Appraisal guidelines. RFID tags are developed to prevent surgical instruments retained in the body and secondary infections by allowing for the recording of usage history of instruments and to properly manage them.

In the results, it became evident that the secondary infection risk is low from surgical instrument with RFID tags attached, and therefore, surgical instruments with RFID tags attached should be used for traceability and safer management.

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