2021 43rd Annual International Conference of the
IEEE Engineering in Medicine & Biology Society (EMBC)
Oct 31 - Nov 4, 2021. Virtual Conference

Examination of a contact detection sensor to prevent self-removal of peripheral intravenous catheters*

Ayumi Amemiya, Aya Matsumura, Ryutaro Kase, Yasuhisa Sugasawa, Takashiro Minowa, and Makoto Ichida

***Abstract*— If patients are at risk of self-removal of a catheter, it is necessary to check the condition of the catheter frequently. If this is the only way to prevent self-removal, physical restraint of the patient is required. Furthermore, it is currently necessary to reduce human-to-human contact to prevent COVID-19 infection. Therefore, the development of a sensor system to prevent self-removal of a catheter and reduce human-to-human contact is urgent. The purpose of this study is to examine a sensor system that detects the contact of a patient's hand to a peripheral intravenous catheter in order to prevent self-removal in patients with dementia. This study analyzes the use of a capacitance sensor and an energization sensor to detect the contact of a patient's hand to a catheter. Additionally, the time required from the start of peeling the sensor sheet to the removal of the needle was measured. As the results, the capacitance sensor was difficult to use in a clinical setting because the connection between the seat and cable could be unstable depending on the condition of the connections. The energization sensor was able to recognize the contact of a hand to the catheter by detecting its contact with the sensor. It took at least 28 seconds from detection of the hand contact to the beginning of needle removal. Therefore, it is possible for the caregiver to visit the patient's bedside and stop the self-removal when the sensor sheet detects hand contact. This study is the first step in developing the system that prevents self-removal by detecting hand contact and requires several more steps for clinical use. In the future, we will conduct surveys on more subjects and clinical trials on elderly with dementia to examine accuracy, precision, and repeatability. Using the energization sensor, a self-removal prevention system for dementia patients will be further developed.**

***Clinical Relevance*— Developing this self-removal prevention system in the future will allow many dementia patients to no longer be physically restrained, and it will make it possible to remotely detect their actions to prevent self-removal while also minimizing the risk of COVID-19 infection.**

I. INTRODUCTION

Physical restraint of patients is used to reduce injuries from falling and accidental self-removal of tubes and intravascular lines [1, 2]. Japan's Ministry of Health, Labor, and Welfare recognizes 11 types of physical restraints, and these 11 acts can all be classified into these two purposes. To help prevent accidents, mats and clip sensors, used in hospital and healthcare facilities [3]. To reduce the physical restraint use, some researchers are developing systems that use depth sensors to detect motion and prevent patients from falling, for example [3, 4]. A study examined the use of wearable technology to monitor a patient's physical activity, sleep posture, and heart rate variability as potential markers of the risk of falling [5]. Another study explored sensing changes in a patient's leg angles to decrease the chances of falling [6].

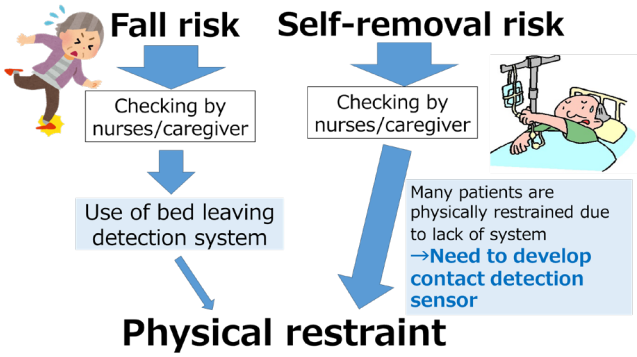

Figure 1. Lack of self-removal prevention sensor system

There is no such system to prevent catheter self-removal, however (Figure 1). Although there are some commercially available sensors, those only detect bleeding once it starts after self-removal [7]. There is developing technology that attempts to sense the movement or shifting of an intravenous line when it is pulled on [8], but this can only be detected a few seconds before removal, so caregivers do not have time to take actions to prevent it. Thus, there is no system that can prevent self-removal other than checking the condition of the catheter frequently, so physical restraint of the patient is inevitable (Figure 1). Furthermore, it is currently necessary to reduce human-to-human contact to prevent COVID-19 infection. If patients at high risk of self-removal are not physically restrained and it is necessary to continuously confirm that the patient has not removed the catheter, there is a high risk of infection for both the patient and the caregiver. Therefore, reducing contact using a sensor system to prevent self-removal is an urgent issue.

Patients are at high risk of catheter self-removal either due to delirium in an intensive care unit, when they pull the

*Research supported by Mitsui Sumitomo Insurance Welfare Foundation.

Ayumi Amemiya is with Graduate School of Nursing, Chiba University, Chiba, JAPAN (corresponding author to provide phone: +81(0)43-226-2402; fax: +81(0)43-226-2403; e-mail: amemiya-a@chiba-u.jp).

Aya Matsumura and Ryutaro Kase are also with Graduate School of Nursing, Chiba University, Chiba, Japan (e-mail: ayamm@chiba-u.jp, rkase@chiba-u.jp).

Yasuhisa Sugasawa, Takashiro Minowa, and Makoto Ishida are with I・MEDEX CO., LTD, Chiba, Japan (e-mail: sugasawa@imedex.co.jp, minowa@imedex.co.jp, m-ichida@imedex.co.jp).

catheter out strongly [9, 10], or when cognitive function is impaired due to dementia [11, 12]. There is no detailed study showing the nature of self-removal, but in our clinical experience, dementia patients do not understand what the catheter is, so they pull it out while checking or touching it. In case of dementia, if it were possible to detect the patient's hand contact the catheter, the caregiver could take notice before it is removed, and self-removal could be prevented. Furthermore, it is not clear how many seconds the nurse needs to go to the patient to prevent self-removal after the sensor detects hand contact. The purpose of this study is to examine the effectiveness of a sensor that detects the contact of a patient's hand to the catheter in order to develop a self-removal prevention system for patients with dementia. Additionally, the time required from the start of peeling the sensor sheet to the removal of the needle is needed to be revealed. This study is the first step in developing the system that prevents self-removal by detecting hand contact and requires several more steps for clinical use. It focuses on the peripheral intravenous catheter in the study, which is the most frequently used medical catheter.

II. METHODS

A. Requirements for the contact detection sensor

A sensor to detect the contact of a patient's hand to the catheter should not be used in a clinical setting unless it has an intuitive design. Thus, a distance sensor was considered first. However, a distance sensor would need to be attached to the patient's finger, and he or she could easily remove it. Therefore, the following were considered as requirements for a contact detection sensor:

- Intuitive, easy to understand
- Few parts to attach
- Detects the hand itself
- The part to be attached on the patient is thin and light

A capacitance sensor and an energization sensor with lights that are turned on and off by the contact of the hand were examined.

B. Examination of the contact detection sensor

The capacitance sensor

The Capacitive Sensor Iot Development Kit with Bluetooth low energy made by Bit Trade One, Ltd. (Sagamihara, Japan) was used (Figure 2). The attached conductive, thin, flexible transparent film was used as the sensor sheet. The film can be freely cut to fit a surface. By combining smartphone applications, it is possible to adjust the sensitivity and threshold values while checking the change in capacitance on the screen. The output numerical value is unique to this application and has no unit. Power was supplied by a button battery and could be used continuously for about 12 hours. This was too short for a clinical setting and needs improvement. The circuit was placed in the case below the sensor seat. The circuit and PC were connected via Bluetooth, the alarm sounded on the PC, and the volume was adjustable. The alarm should be designed to be heard only by the caregiver, as it was expected that the alarm sound would excite or confuse the patients.

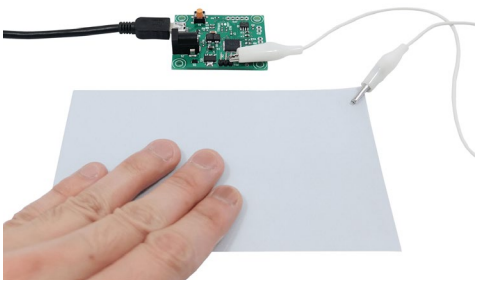

Figure 2. The capacitance sensor

The energization sensor

When the patient's hand completes the circuit, the resistance decreases, and the system can detect hand contact with the sensor sheet (Figure 3). The two circuits were drawn on the insulating sheet using a carbon paste that is resistant to bending (Figure 4). The circuit and battery were integrated, connected to the sensor seat by wire, and placed on an IV (Intravenous) pole. The wiring was about 1 mm in diameter and followed the drip line, so it did not interfere with the behavior of the subject. It could be used continuously for about 3-4 hours by the battery. This was too short for a clinical setting, as well as for research use, and needs improvement. The circuit and PC were connected via Bluetooth, the alarm sounded on the PC, and the volume was adjustable.

Figure 3. Circuit diagram

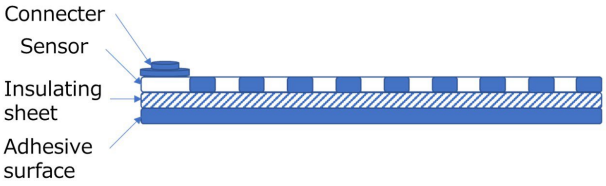

Figure 4. Sensor sheet cross section

C. Procedure

In clinical setting, after fixing the insertion part of the drip needle with a special tape, if patient has a self-removal risk, it was covered with a bandage as shown in Figure 5. Subjects who had experience in dementia care were recruited. A sensor sheet was attached to the bandage, and healthy subjects were asked to simulate the action of removing the catheter to confirm whether or not the motion could be detected. Additionally, the time required from the start of peeling the sensor sheet to the removal of the needle was measured. This study was approved by the Ethical Committee of the Graduate School of Nursing, Chiba University [# R2-31].

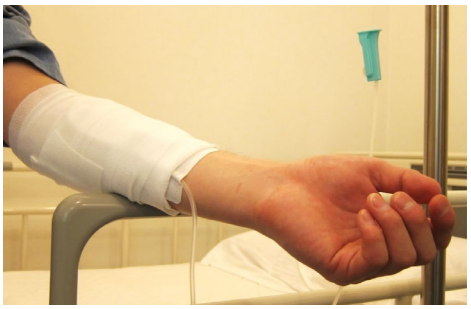

Figure 5. Cover the needle with a bandage to prevent self-removal

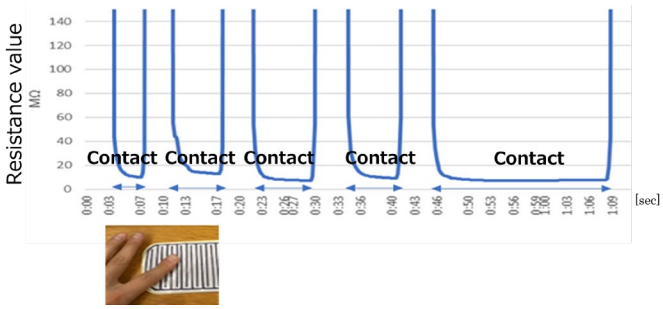

Figure 6. Resistance value of the energization

III. RESULTS

A. The capacitance sensor

The capacitance sensor generates a lot of noise, and it is difficult to detect the contact of the hand using the sheet that comes with the ready-made sensor. The connection between the seat and cable was unstable and generated a lot of noise. Furthermore, even if a shielded cable with a diameter of approximately 2 mm was used, the cable sensed the capacitance of the skin and the surrounding area. Shielded cables thicker than this were difficult to use in a clinical setting due to weight issues. Thus, it was necessary to replace the ready-made sensor. Therefore, we conducted the test using the energization sensor first.

B. The energization sensor

Because the circuit was not completed when there was no hand contact, the resistance value was infinite. When the hand contacted and completed the circuit, the resistance value decreased, and the contact of the hand could be detected (Figure 6).

It was tested in four subjects in their 20s to 80s to check if it could detect the self-removal action. It responded to hand contact in all four subjects and could detect self-removal action. In addition, the sensor did not respond to other motion, such as rolling over or getting up. This means that the sensor solely detected the self-removal action (no false alarm).

The data of subject D is shown in Figure 7. Until about 39 seconds, the motion was not related to self-removal, and the sensor did not react. The subject began to peel off the sensor sheet at about 47 seconds and finished to do so after 1 minute and 3 seconds. The sensor detected the subject contact.

C. Time from the start of self-removal action to remove the needle

The time it took for each subject to begin to remove the sensor sheet, remove the bandages and tape, and begin to remove the needle was also measured. As shown in Table 1, the time from when a subject started the self-removal action of peeling off the sensor sheet to when the needle was first pulled out was 28 to 81 seconds.

Figure 7. Resistance value of the energization sensor

TABLE I. TIME FROM THE START OF SELF-REMOVAL ACTION TO REMOVE THE NEEDLE

	Age	Time taken until removing the needle
Subject A	20s.	28 seconds
Subject B	60s.	33 seconds
Subject C	80s.	81 seconds

IV. DISCUSSION

The system detected the patient's needle self-removal when contacting the sensor sheet attached near the infusion site. In this study, several sensor methods and the time until needle self-removal were examined. The time from the start of self-removal action to remove the needle was also revealed.

A. The energization sensor

The energization sensor was able to detect hand contact. After detecting the hand contact, a caregiver would be able to prevent self-removal by going to the patient's bedside while he or she is removing the bandage before self-removal. The data measured showed no false alarms and almost no noise. The mechanism of the capacitance sensor is easy to understand by any caregiver. Therefore, it meets the requirement of the contact detection sensor of hand, and it is likely to be a clinically usable sensor.

B. Time from the start of self-removal action to remove the needle

It took 28 seconds even for a young subject after the sensor detected the contact of the hand until the needle started to be removed. It took 81 seconds for the elderly subject (80s) who was assumed to use this system. Thus, if a caregiver hurried to the patient shortly after the sensor detected contact, it would be possible to stop the self-removal action. From our clinical experience, that is possible. This shows that by using this novel self-removal prevention system fixed with bandages and tape and affixed with a sensor sheet, self-removal can be prevented without physical restraint and frequent visits to the patient's bedside.

V. CONCLUSION

It is possible to make a system that prevents the self-removal of peripheral intravenous catheters by detecting the contact of a hand using the energization sensor. It takes at least 28 seconds from detection of the hand contact to the beginning of needle removal. Therefore, it is possible for the caregiver to visit the patient's bedside and stop the self-removal when the sensor sheet detects hand contact. This system may make the prevention of self-removal possible without the use of physical restraints and frequent visits to the patient's bedside. The prevention of self-removal using this system must be tested further. In the future, we will conduct surveys on more subjects and clinical trials on elderly with dementia to examine accuracy, precision, and repeatability. In addition, although we focused on peripheral intravenous catheters in this study, it is necessary to develop a sensor sheet that can also be used for nasogastric tubes, respirators, and other medical catheters.

ACKNOWLEDGMENT

We would like to thank all the subjects of this study. There is no conflict of interest to disclose.

REFERENCES

[1] Z. M. Franks, J. A. Alcock, T. Lam, K. J. Haines, N. Arora, and M. Ramanan, "Physical restraints and post-traumatic stress disorder in survivors of critical illness: a systematic review and meta-analysis," *Ann Am Thorac Soc*. 2020, (ahead of print).

[2] P. Werner, "Perceptions regarding the use of physical restraints with elderly persons: comparison of Israeli health care nurses and social workers," *J Interprof Care*. vol. 16, no. 1, pp. 59–68, Jan. 2002.

[3] H. Komagata, E. Kakinuma, M. Ishikawa, K. Shinoda, and N. Kobayashi, "Semi-automatic calibration method for a bed-monitoring system using infrared image depth sensors," *Sensors (Basel)*. vol. 19, no. 20, pp. 4581, Jan. 2019.

[4] P. Potter, K. Allen, E. Costantinou, W. D. Klinkenberg, J. Malen, T. Norris, E. O'Connor, W. Roney, H. H. Tymkew, and L. Wolf, "Evaluation of Sensor Technology to Detect Fall Risk and Prevent Falls in Acute Care," *Jt Comm J Qual Patient Saf*. vol. 43, no. 8, pp. 414–421, Aug. 2017.

[5] J. Razjouyan, B. Najafi, M. Horstman, A. Sharafkhaneh, M. Amirmazaheri, H. Zhou, M. E. Kunik, and A. Naik, "Toward using wearables to remotely monitor cognitive frailty in community-living older adults: an observational study," *Sensors (Basel)*. vol. 20, no. 8, pp. 2218, Jan. 2020.

[6] N. J. Raden, U. Kulau, M. Marschollek, and K. H. Wolf, "INBED: A highly specialized system for bed-exit-detection and fall prevention on a geriatric ward," *Sensors (Basel)*. vol. 19, no. 5, pp. 1017, Jan. 2019.

[7] C. Y. Chionh, D. Y. Soh, C. H. Tan, J. Y. Khaw, Y. C. Wong, and S. Foon, "A device for surveillance of vascular access sites for bleeding: results from a clinical evaluation trial," *Sci Rep*. vol. 10, no. 1, pp. 18153, Oct. 2020.

[8] T. Watanabe, K. Maeda, M.Tokaji, M. Takeuchi, and H. Tobata, "Research and development of a system that senses removal (movement) of infusion line using a reed switch," *Iryo kiki gaku*. vol. 89, no. 1, pp. 12–20, 2019. (in Japanese)

[9] M. Suliman, "Prevalence of physical restraint among ventilated intensive care unit patients," *J Clin Nurs*. 27(19-20):3490-3496, Oct. 2018.

[10] C. Lane, and A. Harrington, "The factors that influence nurses' use of physical restraint: a thematic literature review," *Int J Nurs Pract*. vol. 17, no. 2, pp. 195–204, Apr. 2011.

[11] H. Hofmann, and S. Hahn, "Characteristics of nursing home residents and physical restraint: a systematic literature review," *J Clin Nurs*. vol. 23, no. 21-22, pp. 3012–3024, Nov. 2014.

[12] M. J. M. Gulpers, M. H. C. Bleijlevens, E. Capezuti, E. van Rossum, T. Ambergen, and J. P. H. Hamers, "Preventing belt restraint use in newly admitted residents in nursing homes: a quasi-experimental study," *Int J Nurs Stud*. vol. 49, no. 12, pp. 1473–1479, Dec. 2012.