2022 44th Annual International Conference of
the IEEE Engineering in Medicine & Biology Society (EMBC)
Scottish Event Campus, Glasgow, UK, July 11-15, 2022

2022 44th Annual International Conference of the IEEE Engineering in Medicine & Biology Society (EMBC) | 978-1-7281-2782-8/22/$31.00 ©2022 IEEE | DOI: 10.1109/EMBC48229.2022.9871840

ATTENTIV: Instrumented Peripheral Catheter for the Detection of Catheter Dislodgement in IV Infiltration*

Jessica Y. Bo[1], Kevin Ta[1], Rio Nishida[1], Gordon Yeh[1], Vivian W. L. Tsang[1], Megan Bolton[1], Manon Ranger[1], and Konrad Walus[1]

Abstract— **Intravenous (IV) infiltration is a common problem associated with IV infusion therapy in clinical practice. A multitude of factors can cause the leakage of IV fluids into the surrounding tissues, resulting in symptoms ranging from temporary swelling to permanent tissue damage. Severe infiltration outcomes can be avoided or minimized if the patient's care provider is alerted of the infiltration at its earliest onset. However, there is a lack of real-time, continuous infiltration monitoring solutions, especially those suited for clinical use for critically ill patients. Our design of the sensor-integrated ATTENTIV catheter allows direct detection of catheter dislodgement, a root cause of IV infiltration. We verify two detection methods: blood-tissue differentiation with a support vector machine and signal peak identification with a thresholding algorithm. We present promising preliminary testing results on biological and phantom models that utilize bioimpedance as the sensing modality.**

Clinical relevance— **The sensor-embedded ATTENTIV catheter demonstrates potential to automate IV infiltration detection in lieu of using traditional infusion catheters and manual detection methods.**

I. INTRODUCTION

Intravenous (IV) infusions are used in 60-90% of hospitalized patients to administer medication, hydration, and nutrition, primarily through the peripheral veins. The failure rate of IV infusions can be as high as 50%, with a leading cause being IV infiltration (or extravasation, in the case of vesicant drugs) [1]. Clinically, an infiltration is described as the leakage of IV fluids into surrounding tissues outside of the blood vessel. This is influenced by a variety of factors, including compromised vessel integrity or external forces and movements [2]. The most common cause of catheter failure is dislodgement, which is when the plastic tubing of the IV catheter penetrates through or slips out of the patient's vein [3]. Rates of IV infiltration vary widely and may also be underestimated due to inconsistent reporting by hospitals. A review reported an average infiltration rate of 24% (16-34%) in the adult population [1]. The incidence rate is higher among the neonatal population, where 50-70% of neonatal intensive care unit (NICU) patients experience infiltration [4] and 4% result in permanent scarring from tissue necrosis [5].

The leakage of IV fluids leads to local tissue swelling and edemas. Vesicant drugs can cause blistering and necrosis of local tissues. The most severe cases of infiltration results in extended hospital stays, reconstructive surgery, and amputation of the affected limb [6]. Infiltration is difficult to prevent due to the unpredictability of the underlying factors, thus clinicians (often nurses) perform regular monitoring of symptoms. Externally visible or palpable symptoms of infiltration include skin redness, swelling, blanching, and textural and temperature changes [7], [8], [9]. Patients can also report pain, but this is not always possible for non-verbal or unconscious patients. In addition, relying on the presentation of visible or palpable symptoms can delay treatment for the patient, while tissue damages worsen as infiltration continues.

Another method that care providers rely on to detect infiltration is through pressure sensors in infusion pumps that alarm when buildup or blockage is detected in the infusion line. However, pressure build ups have varying causes, such as kinking in the catheter or tubing, making it difficult for clinicians to trace the problem [7]. Additionally, infiltration does not always result in blockage of flow and may not trigger the alarm at all [10].

Although uncommon in clinical practice due to their recency, various external physiological sensors have been studied for their efficacy in providing early detection of infiltration. Several groups developed external patch sensors which measures properties like changes in skin strain and tissue bioimpedance caused by the accumulation of IV fluids [11], [12], [13], [14]. The company ivWatch produces an optical sensor that detects presence of excess fluids at the IV site, which is regulatory-approved in several markets [15].

However, external sensors are not suited for all environments. For example, an environment like the NICU is already crowded with machines, tubing and wiring, so it is preferable to avoid any additional equipment [16], [17]. The adhesive patches developed by the other groups may damage or irritate the more fragile skin of premature babies [18], as well as other critically ill and vulnerable patient groups like the elderly or medically-compromised. Current technological solutions on the market and under development would not fit the desired clinical specifications for all vulnerable patients, leaving an unmet need. Bosque [19] presented a pump-integrated IV monitoring system that predicts the onset of infiltration using a fusion of several physiological signals from the tip of the catheter. While the design is intended for the neonatal population, it has not been verified clinically.

In this paper, we present the design of the ATTENTIV IV catheter that uses bioimpedance to detect infiltration. Instead

*This work was not supported by any organization

[1]JB and KT are with the Mechanical Engineering Department, RN is with the Integrated Engineering Program, GY and KW are with the Electrical and Computer Engineering Department, VT is with the Faculty of Medicine, and MB and MR are with the School of Nursing at the University of British Columbia, Vancouver, BC V6T 1Z4, Canada. {jessica.bo, kevinta} @alumni.ubc.ca

of measuring indirect symptoms of infiltration with external sensors, our system intends to make real-time predictions of the infusion status with only the catheter. We also show preliminary prototyping results on animal tissue and gelatin phantom models. ATTENTIV's design considers the needs of vulnerable hospitalized populations, such as neonates, but can also be applied more broadly to any patient population.

II. Design

In our proposed design, modifications to the catheter to implement bioimpedance sensing capabilities should present minimal changes to clinical standard procedures of IV catheter insertion. Infiltration often involves dislodgement of the catheter, where the catheter moves into the surrounding tissues and leads to an accretion of fluids in interstitial tissues. The instrumented catheter incorporates an embedded sensor at its tip to monitor in-vivo conditions.

In the hand and forearm, where IV infusions are commonly placed, surface-level veins are embedded in fatty connective tissue [20]. The blood vessel and connective tissue exhibit different static bioimpedance characteristics, allowing for blood-tissue discrimination. As a result of the catheter moving from low to high impedance areas, the dislodgement event has distinct dynamic signatures that can provide key information to detect an IV infiltration onset.

The usage of bioimpedance for blood-tissue discrimination has been explored in previous literature. Historical experiments confirm that the conductivity of fat-based tissues is lower than that of water-based tissues [21]. Bioimpedance has been in widespread use for nutrition and clinical research, and continued studies in bioelectrical impedance has shown little to no risk as a sensing modality [22].

Our experimental apparatus incorporates two exposed electrodes at the catheter tip, fabricated from 38G insulated copper wire laid in-line with an 14G catheter (we use a larger-sized catheter comparative to clinical catheters for ease of prototyping). Impedance measurements along a needle-like apparatus have been previously performed in [23]. These wires are connected through SMA connectors to a Digilent PMod IA, an impedance analyzer utilizing an Analog Device AD5933 12-bit impedance converter. This impedance analyzer can generate waveforms up to 100 kHz and detect impedances between 1kΩ to 1MΩ. Fig. 1 shows a prototype catheter with in-laid copper wires and how it connects to the acquisition subsystem. For initial prototyping, we built the system from inexpensive electronic components. We use an Arduino Uno development board for data acquisition to deliver impedance values for processing to a laptop.

The modular design aims to be quickly assembled and disassembled based on need for time efficiency in a clinical setting. Future improvements may leverage sensor miniaturization technologies that have become viable for multi-modal in-vivo conditions [24]. Intrusiveness, usability, and biocompatibility—such as through the use of conductive polymers like PEDOT [29]—are key considerations in the future design of a clinically-compatible prototype.

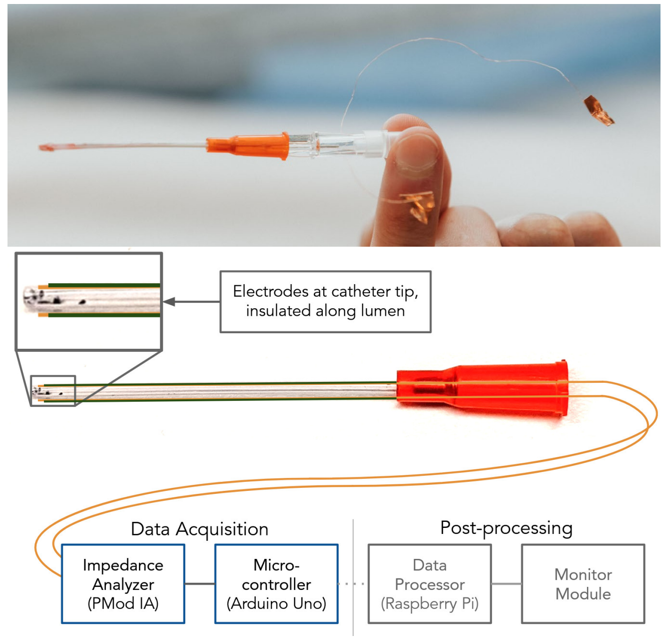

Fig. 1. (Top) Prototype catheter used for experiments. (Bottom) Labelled system schematic.

III. Experiments and Results

To investigate the sensor-embedded catheter, we used two different models that simulate IV catheter cannulation. These models were selected to represent biological and environmental parameters related to cannulation. In additional to the experimental setup, we also present preliminary test results which are intended to verify various aspects of the design (such as using a bioimpedance sensor for tissue discrimination and dynamic signature detection), but not to represent a fully-verified clinical experiment.

A. Biological Model

Past literature demonstrated use of swine-based biological models for infiltration related studies [12], [11]. For our baseline discrimination tests, we used fatty pork tissue and bovine blood as biological substitutes, shown in Fig. 2. The impedance circuit was connected to the catheter probe which punctured the biological models to collect 150 samples per trial. This test was repeated at different undisturbed sites and

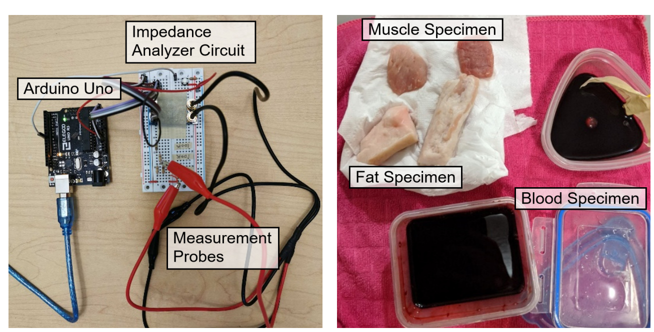

Fig. 2. (Left) Prototype set-up for blood impedance sampling. (Right) Different meat and blood samples for data collection.

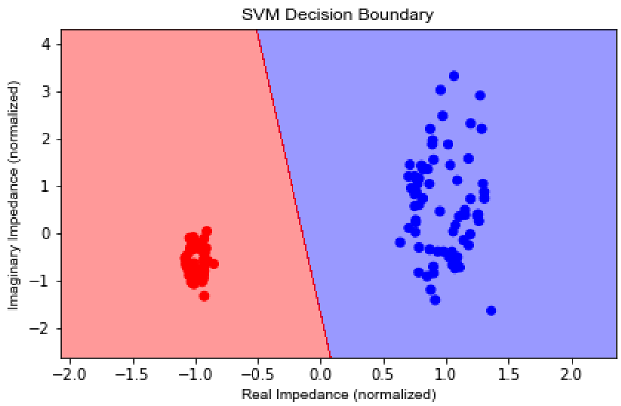

Fig. 3. Decision boundary and classification outcomes for blood (red) and fatty tissue (blue) impedance measurements.

locations within the biological models 2-4 times. This experiment corroborated impedance-based differentiation between blood and fatty tissue on fresh biological samples.

We implemented a support vector machine (SVM) model for tissue classification using the real and imaginary components of the bioimpedance measurements as features. SVM was chosen for this application for its success in binary classification problems, including work in other tissue classification [26], [25]. Figure 3 shows the SVM decision boundaries drawn from the test data for the blood and fat bioimpedance measurements. From the visualization, two clear clusters show that the model achieves 100% accuracy on the test dataset. This confirms that bioimpedance can be leveraged as a feature for tissue differentiation.

B. Phantom Model

Biological models may accurately reflect the complexity of human tissue, but fail to capture the specific environment and procedure of cannulation. A different model is required to simulate the specific mechanics of an IV cannulation. Human tissue can be substituted with non-biological materials, such as gelatin with adjusted conductivity by varying NaCl concentrations in the solution [23]. Past phantom-based models used liquid-filled tubes encased in gelatin or agar to simulate blood vessels in tissue for vein cannulation skill-training [27]. We built a gelatin-encased flow channel where pumped saline solution flowed through a simulated blood vessel. The use of a pulsed peristaltic pump allowed for the simulation of heart-pumped blood flow, controlling for pressurized fluid flow present in IV infiltration. Fig. 4 shows a high level overview of the experimental set-up.

A continuously sampled impedance signal at the catheter tip monitored the catheter tip conditions. The impedance circuit was connected to the probe and operated at 30 kHz. A simulated catheter dislodgement event, shown in Fig. 5, where the catheter pierces and exits the channel into the gelatin encasement, was performed and recorded for infiltration detection.

We use a thresholding algorithm developed by [28], which is based on the principle of statistical dispersion, to identify

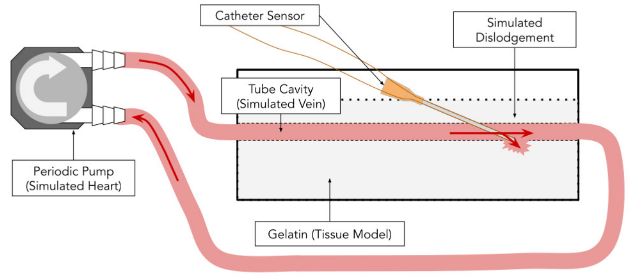

Fig. 4. Gelatin-based phantom with simulated vein flow channel.

spikes in the signal that may be indicative of infiltration. At any given new data point, if its value should fall away from a predetermined standard deviation from the moving average of the signal, it would be detected as a "signal peak". The sensitivity and temporal parameters of the algorithm were fine-tuned to the data. Fig. 6 shows a visualization of the signal and peak detection on data from a recorded infiltration event. The time of infiltration is also estimated.

IV. Discussion

We performed two exploratory tests for infiltration detection, the first by blood-tissue differentiation, and the second by signal peak detection. Bioimpedance was shown to be a viable signal for evaluating the dynamics of the catheter during a dislodgement event. Future iterations of the algorithm can integrate both (or other) methods through weighted contributions determined by physiological data. The final detection method requires further clinical testing to validate and optimize, as our ex-vivo test setups only capture partial physiological signals for infiltration.

Our design of the ATTENTIV catheter is novel from existing solutions through its ability to integrate with existing IV equipment. Without the need for external attachments to the patient, our ecosystem requires minimal additions or changes to the clinical care routine, and would be optimal for patients with fragile skin and vessel integrity, including but not limited to the neonatal population. Through detecting a root cause, catheter dislodgement, as opposed to resulting symptoms, infiltration can be inferred in real-time, which would reduce the time-to-treatment.

An additional unique compatibility feature of ATTENTIV is its possible application to other types of infu-

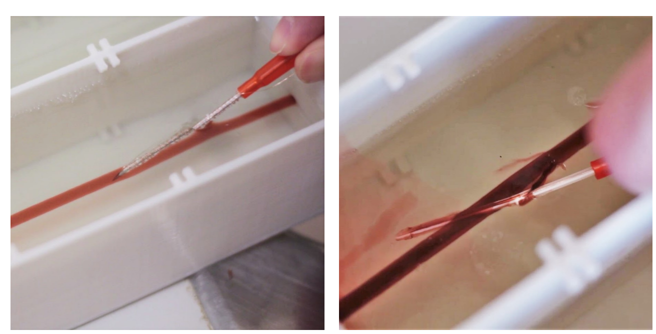

Fig. 5. Gelatin-based phantom model of cannulation for simulated catheter dislodgement.

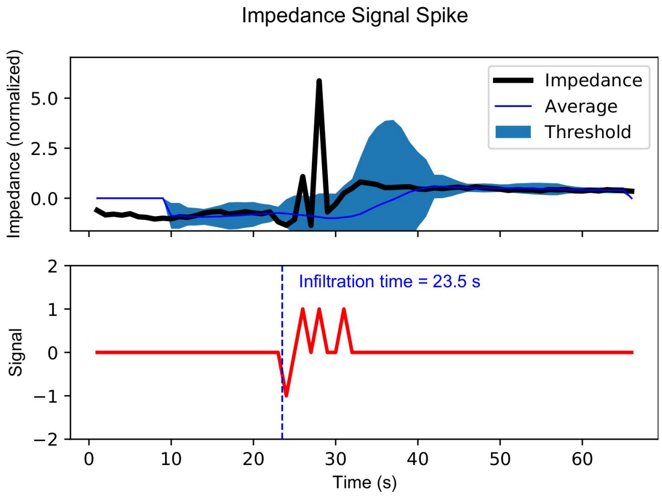

Fig. 6. Sample impedance measurement (top: black line) and the corresponding peaks (bottom: red) with the estimated time of infiltration.

sion catheters, such as central venous catheters, umbilical artery/vein catheters, and arterial catheters. The ability to directly sense physiological conditions from within the body via the catheter can provide grounds for further development for vital signs monitoring or other uses. Further miniaturization of components will also be necessary to adapt the design to smaller catheter sizes that are suitable for a wider range of patients, including the neonatal population.

V. Conclusion

We introduce the ATTENTIV catheter, a sensor-integrated device for detecting IV infiltration caused by catheter dislodgement. Our proof-of-concept device demonstrates strong potential in offline trials performed in animal tissue and phantom models through two detection methods (blood-tissue differentiation and signal peak identification, respectively). The next step of development will be to incorporate real-time processing and predictions, which will enable dynamic infiltration testing in in-vivo animal models.

References

[1] Helm, R. E., Klausner, J. D., Klemperer, J. D., Flint, L. M., & Huang, E. (2015). Accepted but Unacceptable: Peripheral IV Catheter Failure. Journal of Infusion Nursing, 38(3), 189–203.

[2] Dychter, S. S., Gold, D. A., Carson, D., & Haller, M. (2012). Intravenous therapy: A review of complications and economic considerations of peripheral access. Journal of Infusion Nursing, 35(2), 84–91.

[3] Moureau, N. (2019). “Shifting the Standard of Care in IV Dislodgement Prevention.” Infection Control Today, www.infectioncontroltoday.com/infusion-vascular-access/shifting-standard-care-iv-dislodgement-prevention.

[4] Mccullen, K. L., & Pieper, B. (2006). A Retrospective Chart Review of Risk, 48306(April), 133–139.

[5] Wilkins, C. E., & Emmerson, A. J. B. (2004). Extravasation injuries on regional neonatal units. Archives of Disease in Childhood: Fetal and Neonatal Edition, 89(3), 274–275.

[6] Doellman, D., Hadaway, L., Bowe-Geddes, L. A., Franklin, M., LeDonne, J., Papke-O’Donnell, L., Pettit, J., Schulmeister, L., & Stranz, M. (2009). Infiltration and extravasation: update on prevention and management. Journal of Infusion Nursing, 32(4), 203-11.

[7] Amjad, I., Murphy, T., Nylander-Housholder, L., & Ranft, A. (2011). A new approach to management of intravenous infiltration in pediatric patients: Pathophysiology, classification, and treatment. Journal of Infusion Nursing, 34(4), 242–249.

[8] Yosowitz, P., Ekland, D. A., Shaw, R. C., & Parsons, R. W. (1975). Peripheral intravenous infiltration necrosis. Annals of Surgery, 182(5), 553–556.

[9] Schulmeister, L. (2007). Infiltration and extravasation. American Journal of Nursing, 107(10), 16.

[10] Huber, C. & Augustine, A. (2009). IV Infusion Alarms: Don’t Wait for the Beep. American Journal of Nursing, 109(4), 32–33.

[11] Lim, R., Cheng, M. Y., Damalerio, R., & Chen, W. (2017). Simulation Analysis of a Conformal Patch Sensor for Skin Tension and Swelling Detection. Electronic Components and Technology Conference, 2104–2109.

[12] Jambulingam, J. A., McCrory, R., West, L., & Inan, O. T. (2016). Non-invasive, multi-modal sensing of skin stretch and bioimpedance for detecting infiltration during intravenous therapy. Annual International Conference of the IEEE Engineering in Medicine and Biology Society, EMBS, 2016-October, 4755–4758.

[13] Bicen, A. O., West, L. L., & Cesar, L. (2018). Toward Non-Invasive and Automatic Intravenous Infiltration Detection : Evaluation of Bioimpedance and Skin Strain in a Pig Model. IEEE Journal of Translational Engineering in Health and Medicine, 6(February), 1–7.

[14] Mabrouk, S., Rodriguez, Z., De, S., Maher, K., West, L., Pogue, L., Parker, A., Srivatsava, A., Sonti, A., & Inan, O. T. (2020). Multi-modal local physiological sensing at the intravenous catheter insertion site : Towards automated IV infiltration detection. 2020 IEEE SENSORS.

[15] Wintec LW. (2005). Optical detection of intravenous infiltration, US 7,826,890 B1, USA. http://www.google.com/patents/US7826890

[16] Chen, W., Nguyen, S. T., Coops, R., Oetomo, S. B., & Feijs, L. (2009). Wireless transmission design for health monitoring at neonatal intensive care units. 2nd International Symposium on Applied Sciences in Biomedical and Communication Technologies, ISABEL 2009.

[17] Rhine, W. D. (2016). Technology – Considerations for the NICU of the Future. In Newborn and Infant Nursing Reviews 16(4), 208–212.

[18] Lund, C. (2014). Medical Adhesives in the NICU. Newborn and Infant Nursing Reviews, 14(4), 160–165.

[19] Bosque, E. (2020). Development of an Alarm Algorithm, With Nanotechnology Multimodal Sensor, to Predict Impending Infusion Failure and Improve Safety of Peripheral Intravenous Catheters in Neonates. Advances in Neonatal Care, 20(3), 2330–243.

[20] Standring, S. (2011). “Forearm” in Gray’s Anatomy The Anatomical Basis of Clinical Practice, ch 49, Figure 49.17.

[21] Gabriel, C., Gabriel, S., & Corthout, E. (1996) The dielectric properties of biological tissues: I. Literature survey. Phys. Med. Biol., vol 41, 2231–2249.

[22] Garlini, L. M., Alves, F. D., Kochi, A., Zuchinali, P., Zimerman, L., Pimentel, M., Perry, I. S., Souza, G. C., & Clausell, N. (2020). Safety and Results of Bioelectrical Impedance Analysis in Patients with Cardiac Implantable Electronic Devices. Brazilian Journal of Cardiovascular Surgery, 35(2), 169–174.

[23] Helen, L., O’Donnell, B. D., Messina, W., O’Mahony, C., Ahmed, O. M. A., & Moore, E. J. (2017) . Impedance Sensor to Detect Substance Change at the Needle Tip. Electroanalysis, 29(11), 2533–2540.

[24] Clark, T. M., Malpas, S. C., McCormick, D., Guild, S. J., & Budgett, D. M. (2015). New multimodal data obtained in-vivo from a single ultra-miniature transducer. Biomedical Microdevices, 17(4).

[25] Dunne, E., Santorelli, A., Mcginley, B., Leader, G., O’Halloran, M., & Porter, E. (2018). Supervised Learning Classifiers for Electrical Impedance-based Bladder State Detection. Scientific Reports, 8(1).

[26] Grewal, P. K., & Golnaraghi, F. (2014). Pilot study: Electrical impedance based tissue classification using support vector machine classifier. IET Science, Measurement & Technology, 8(6), 579–587.

[27] Di Domenico S., Santori G., Porcile E., Licausi, M., Centanaro, M., Valente, U. (2007). Inexpensive homemade models for ultrasound-guided vein cannulation training. J Clin Anesth, 19(7), 491–496.

[28] Brakel, J.P.G. van (2014). ”Robust peak detection algorithm using z-scores”. Stack Overflow. URL: https://stackoverflow.com/questions/22583391/peak-signal-detection-in-realtime-timeseries-data/22640362#22640362 (2020-11-08).

[29] Khodagholy, D., Gelinas, J. N., Thesen, T., Doyle, W., Devinsky, O., Malliaras, G. G., Buzsáki, G. (2015). NeuroGrid: recording action potentials from the surface of the brain. Nature neuroscience, 18(2), 310-315.