Design and Applicability of a Mechanical Impedance Sensor for Vein Penetration Detection

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***Abstract*— Intravenous needle insertion is typically conducted manually, with needles guided into vessels by feel while looking for a brief flash of blood. This process is imprecise and leads to mispositioned needles, multiple reinsertion attempts, increased procedure time and higher costs for the hospital. We present a method for indicating that the needle has reached the vein by measuring the change in mechanical impedance of the needle as it passes through different tissue layers. Testing in a phantom indicated that this has the potential to identify transitions through tissue boundaries.**

***Clinical Relevance*— With further characterization and miniaturization, measuring mechanical impedance while a needle is inserted has the potential to address the "blind puncture access" challenge in veins, arteries and other organs.**

I. Introduction

Peripheral venous needle insertion is one of the most common invasive procedures performed. This includes blood draws (phlebotomy/venipuncture) and intravenous (IV) catheter placement. The first is estimated to be performed more than 1 billion times annually worldwide [1] and the second is employed in up to 80% of all hospitalized patients as well as many outpatients, with an estimated 300 million peripheral IV catheters sold yearly [2]. Despite the frequency, needle insertion techniques have not developed substantially beyond the use of simple tourniquet and manual "by feel" needle placement [3].

The most common complications during peripheral venous needle insertion include repeat punctures [4], hematomas, bruising at the site of puncture, fainting, nerve damage [5], and phlebitis [6]. The first two complications are caused by the inherent difficulty in inserting the needle with the correct angular placement and depth into the target vein. Success rates on the first attempt are highly variable. One guidance article states, "there is no mathematical formula that can tell which is the right vein, the right needle, the right angle and the right force that will give the perfect blood draw" [7]. For IV insertions, 30 to 50% of patients require re-insertion attempts [4], and in 10% of venipuncture cases a blood draw requires at least 21 minutes or even an hour, as opposed to the average completion time of 6 minutes in the faster half of the procedures [3]. For elderly and pediatric patients, the average success rates are even lower [7]. In addition to taking more time and delaying the administration of fluids or medications via IV cannulation [8], re-insertion of needles causes significant patient distress [7]. Pediatric respondents rank peripheral intravenous cannula placement as the leading source of procedure related pain [7].

This paper presents the development of a method for detecting needle entry into a vein, based on mechanical impedance, and the evaluation of a proof-of-concept prototype in a tissue phantom.

II. Design Approach

A. Functional Requirements

Prior art for blind needle puncture has largely focused on imaging or on electrically measuring tissue properties. From examining the prior art and current procedure, the following functional requirements were set:

Sensor function: Clearly identifies when the needle has arrived at the correct position and entered the vein
Response time: Detection equal or faster than that of a clinician inserting a needle by feel
Safe: No risk of additional tissue damage
Easy to integrate: Can be used with standard blood draw equipment

B. Measurement Method Selection

Critical to our design was the selection of the type of signal to measure as an indication of needle position. Previous studies have shown the success of using mechanical impedance to measure small differences in tissue properties of soft tissue for research [9] and additional studies have shown that vibrating a needle at certain frequencies, including in the low acoustic range, can decrease the force required to insert the needle and consequently reduce the pain patients experience [10]. Therefore, we hypothesized that a dynamic measure of mechanical impedance would be particularly appropriate for detecting boundaries between tissue types, and thus identifying vein entry.

Methods, including ultrasound, near-infrared imaging, acoustic emission, CT/MRI, electrical impedance and pressure sensing, all face challenges with cost, accuracy, reliability and consistency between patients.

C. Mechanical Impedance Background

Mechanical impedance is a measure of the dynamic response of the system to a driving input force. Sinusoidal excitations are commonly used to characterize soft materials,

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but, to our knowledge, mechanical impedance has not been used in this application.

Mechanical impedance, Z, describes the ratio of an output force to an input velocity, both in this case chosen to be sinusoidal.

$$Z = \frac{F}{V} \tag{1}$$

In our application, the goal is to identify differences in the stiffness, k, and damping, c, between various tissue layers. Reframing Z to pull out these terms, we arrive at:

$$Z = j\omega m + c + \frac{k}{j\omega}. \tag{2}$$

where m, k, and c are the combined response of the tissue layers for a given needle depth, and ω is the oscillation frequency of the input force. When a voice coil is used to apply the excitation force, the current draw can be measured to detect changes in the magnitude of mechanical impedance.

D. Puncture Modeling

Human tissue is typically modeled as a viscoelastic material, but in the discipline of puncture modeling, the critical model is the interaction between the needle and the tissue [11]. The puncture force between the needle and the tissue can be broken into 3 components, as described in (3) [11].

$$f_{total} = f_{stiffness} + f_{friction} + f_{cutting} \tag{3}$$

Various models for each of the terms in Eq (3) have been proposed [11]. The total force is affected by the mechanical properties of each layer, including stiffness, viscosity, and mass. An appropriate model for this application must account for the different skin layers and vein, as well as the relative motion during vibration of the needle. Future work on this project would include further development of an accurate model and comparison with the force results from our experiments.

E. System Architecture

To investigate impedance measurement, we designed a proof-of-concept experimental device to apply a controlled vibration to a needle, while inserting it with a force tester. The system, shown in on the left in Fig 1, interfaces with an eXpert 560x universal force/displacement testing machine (Admet, Norwood, USA). The needle is actuated with a HVCM-019-022-003-02 voice coil (Moticont, Van Nuys, CA, USA) which is guided by two spring steel flexures and coupled via stacked wave springs to the testing machine. A standard luer lock connector at the base interfaces with a standard 21-gauge needle.

Two flexures attached to the voice coil both constrain the motion of the coil without friction and control the resonance frequency of the device. We designed our flexures to allow for tuning in order to test a range of predetermined resonance frequencies by varying the thickness of the material. We began testing with a frequency of 76 Hz. Aqueous gelatin-based phantoms are commonly used as tissue models and we selected this frequency to lie within the range where prior investigators found a significant difference between the mechanical impedance of gels of different water contents [9].

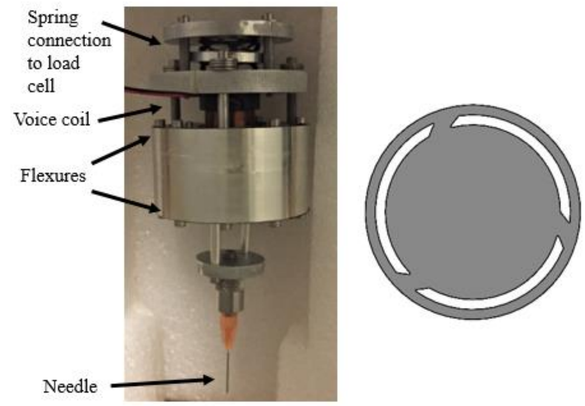

Figure 1. On the left, photo of the experimental device developed for measuring mechanical impedance. On the right, CAD file of the flexure waterjet cut out of spring steel.

III. Experimental Setup and Methods

A. Experimental Setup

The device was mounted to the eXpert 560x testing machine, and then driven by a sinusoidal output from a function generator fed through a power amplifier. The device was driven at the 76 Hz natural frequency and with a driving current of 0.27 amps. Both the driving current and voltage were measured through a LabJack T7 data logger (LabJack, Lakewood, CO, USA) streaming to a computer. The eXpert 560x also recorded force versus time data during the insertion and streamed that data back to the same computer, using an SMT Overload Protected S-Type load cell (Interface Force Measurement Solutions, Scottsdale, Arizona, USA). The two data streams were time synced using the computer system's time stamp. A diagram is shown in Fig. 2.

Standard 21-gauge 25 mm long needles were used and changed between each trial. This setup allowed us to collect preliminary data, with a simple testing device and phantom.

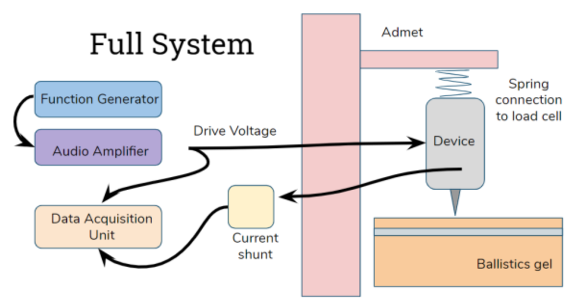

Figure 2. Full system diagram of the test setup.

B. Phantom Construction

The venipuncture phantom was constructed from layers of Vyse ballistics gelatin (Schiller Park, IL) mixed in differing ratios with water. For all layers, Type A gelatin with a bloom score of approximately 250 was used. We constructed the epidermis, dermis and hypodermis following a recipe in [13], casting into a plastic container, as shown in Fig. 3. The vein walls were mimicked with 6.35 mm diameter penrose drain tubing, recommended by the clinician and similar to those used by [14]. The tubes were filled with a glycerol/water mixture at 40% glycerol by volume with a couple drops of food coloring added for visibility [15].

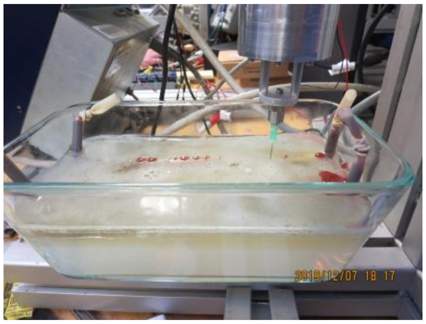

Figure 3. Test setup with gelatin phantom, penrose tube vein with dyed glycerol/water mixture as substitute for blood.

C. Testing Protocol

The test protocol was designed to evaluate the viability of a voice coil and flexure design to determine tissue transitions. Tests were conducted into the tissue without vibration, into the tissue with vibration, into the vein without vibration and into the vein with vibration.

The device was advanced at a rate of 1 mm/s into a gelatin phantom, a rate that is within the range of clinical insertion speeds reported in [12]. Each trial was stopped at a depth of 22 mm from the surface of the phantom. This was consistent with the needle puncturing both sides of the vein.

IV. Preliminary Results & Discussion

A representative sample test where a vibrating needle enters the tissue, punctures the phantom vein and exits the far side is shown in Fig. 4. The load cell reference signal was used as “ground truth” to indicate when the initial puncture into the vein had occurred and this puncture is visible at approximately 16.3 seconds. Notable changes in the average current amplitude occur when the needle enters the tissue and again when the needle enters the phantom vein. While the transitions are small in magnitude, approximately 3% of the baseline value, they were consistently present.

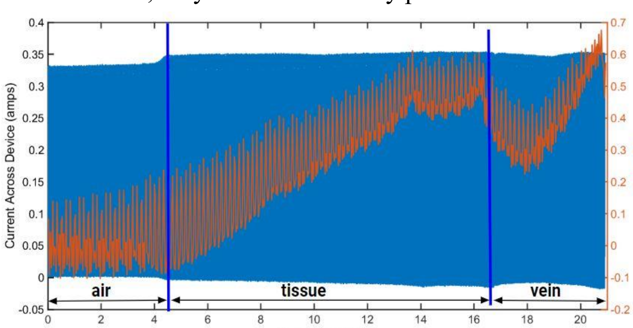

Figure 4. Preliminary results, single representative run, puncture with vibrating needle, demonstrates current can be used to indicate vein depth. Current data in blue sampled at 10 kHz, force data in red sampled at 50 Hz.

Fig. 5 shows a sample baseline test with a non-vibrating needle puncturing through the vein. Clear indicators of both the initial puncture and when the needle exits the vein are present. As expected, the magnitude of the overall force of puncture is higher in the non-vibrating test. The signal at the location of puncture is more clearly visible in the force sensor signal than in the current signal. The percent change in the magnitude of the force signal between the point of puncture and the lowest force measured inside the phantom vein was evaluated for both the vibrating and the non-vibrating insertion. This percent change in magnitude of force measured was dramatically higher with a vibrating needle insertion, at 61.94% versus 10.48% for the non-vibrating needle insertion. This suggests it might be worthwhile to integrate a force measurement into a vibrating device for vein penetration indication, as it may produce a clearer signal than the current measurement.

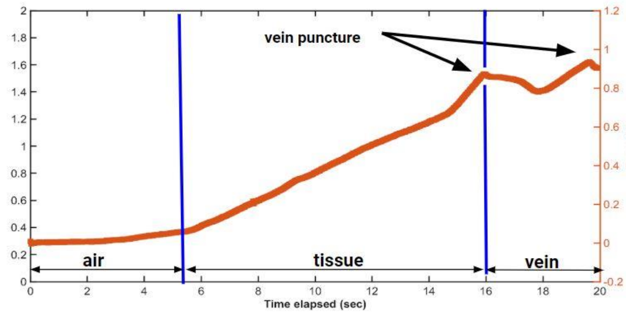

Figure 5. Force results, puncture with non-vibrating needle. Clear signals occur at the point of puncture. Force data was sampled at 50 Hz.

In addition to looking at the raw voltage data, we calculated the electrical impedance of the driving voice coil, by dividing the driving voltage by the current drawn, as increases in mechanical impedance in different layers would be reflected in an increase in the electrical impedance as the voice coil attempted to compensate.

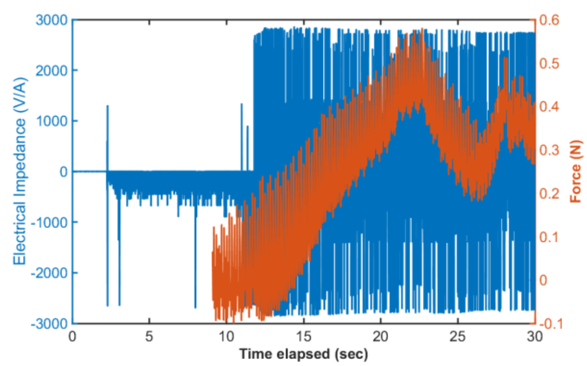

Figure 6. Preliminary results, single representative run, venous puncture with vibrating needle, plot of force on load cell in red and electrical impedance of voice coil over duration of run in blue.

In Fig. 6, from 0 seconds to about 13 seconds, while the needle travels through air, impedance is visibly low. When the needle enters the phantom tissue, the magnitude of the signal increases significantly. This provides a very good indicator of when the device is in the air. However, there is no clear visual signal in the electrical impedance of when the needle penetrates the vein in this plot, due to excessive noise. With further signal processing, we may be able to derive an indicative signal of vein puncture as well as tissue puncture from this data.

While these results are preliminary, they are sufficiently compelling to continue with further testing with a range of flexures and corresponding frequencies, on increasingly accurate phantoms, and to improve our signal processing.

V. Initial Feasibility Assessment

The ultimate goal would be to use such a device in the clinical setting. To assess packaging feasibility, rough initial sizing calculations were made for the voice coil. By using Lorentz force calculations and assuming a B field strength of 1 T, use of 30-gauge copper wire, and a desired output force of 1.2 N, the authors believe a spool diameter of 0.5 cm by a length of 3 cm is an achievable. Clever design and further thought should allow this to scale down further. The length to diameter ratio can of course be adjusted as necessary.

The final device will be designed to intended oscillate in the audible frequency range (50- 500 Hz) as this has been identified as less damaging to tissue than ultrasonic vibration [10]. Our experimental device consumed an average 0.16 watts. We believe final clinical devices could achieve at or below this power level.

VI. Conclusion and Future Work

These initial results indicate that mechanical impedance is a promising sensing method in this application, although more signal processing work is required to achieve greater resolution and faster response. In terms of addressing the initial functional requirements:

Sensor function: The preliminary results show that current, as a proxy for mechanical impedance, can be used to indicate that the needle has reached the vein.

Response time: The indication begins when the needle enters the vein, which gives the clinician a minimum of 1.3 seconds to react and stop inserting the needle. This is longer than the average human reaction time of 0.213 seconds for a visual signal [16] or 0.187 seconds for an audible signal [17].

Safe: This method is safe and likely less harmful to the patient than other methods, due to reduced insertion force. By providing an indication of needle entry into a vein, the device will reduce the number of failed insertion attempts.

Easy to integrate: While the test device itself does not lend itself to easy integration with standard equipment, the concept does and future iterations would focus on miniaturization and packaging.

Our experimental device and setup will be used to conduct further testing to characterize mechanical impedance as an indicator of vein puncture. By swapping out flexures on the designed device, testing will be conducted across a range of resonance frequencies. We intend to develop further analytical characterizations of the tissue layers and the needle response during puncture to better predict expected results.

We will continue with signal processing, including looking at the frequency response of the signal, and increase the resolution of the force data. We will investigate adding integrated force sensing into the device, begin testing with a human holder, and work on reducing the size of the device. Due to the impact of the current COVID-19 pandemic, further testing has been delayed.

We hope these steps will eventually place mechanical impedance-based sensing into the hands of clinicians and that its clear signal will help the numerous patients coming in for a blood draw or IV insertion who want to be pierced by a needle directly and as painlessly as possible.

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References

[1] H. Ogden-Grable and G. W. Gill, "REVIEW: Phlebotomy Puncture Juncture: Preventing Phlebotomy Errors--Potential For Harming Your Patients," *Laboratory Medicine*, vol. 36, no. 7, pp. 430–433, Jan. 2005.

[2] A. Sabri, J. Szalas, K. S. Holmes, L. Labib, and T. Mussivand, "Failed attempts and improvement strategies in peripheral intravenous catheterization," *Bio-Medical Materials and Engineering*, vol. 23, no. 1-2, pp. 93–108, 2013.

[3] C. Ialongo and S. Bernardini, "Phlebotomy, a bridge between laboratory and patient," *Biochemia Medica*, pp. 17–33, Feb. 2016.

[4] G. Walsh, "Difficult Peripheral Venous Access: Recognizing and Managing the Patient at Risk," *Journal of the Association for Vascular Access*, vol. 13, no. 4, pp. 198–203, 2008.

[5] *WHO guidelines on drawing blood: best practices in phlebotomy*. Geneva, Switzerland: WHO Press, 2010.

[6] R. L. Frank, A. B. Wolfson, and J. Grayzel, "Peripheral Venous Access in Adults," *UpToDate*, Nov. 2019.

[7] M. Cooke, A. J. Ullman, G. Ray-Barruel, M. Wallis, A. Corley, and C. M. Rickard, "Not 'just' an intravenous line: Consumer perspectives on peripheral intravenous cannulation (PIVC). An international cross-sectional survey of 25 countries," *Plos One*, vol. 13, no. 2, Feb. 2018.

[8] "Clinical Practice Guideline: Difficult Intravenous Access," Emergency Nurses Association, 2019.

[9] M. Mridha and S. Ödman, "Characterization of Subcutaneous Edema by Mechanical Impedance Measurements," *Journal of Investigative Dermatology*, vol. 85, no. 6, pp. 575–578, 1985.

[10] N. D. Begg and A. H. Slocum, "Audible frequency vibration of puncture-access medical devices," *Medical Engineering & Physics*, vol. 36, no. 3, pp. 371–377, Mar. 2014.

[11] C. Yang, Y. Xie, S. Liu, and D. Sun, "Force Modeling, Identification, and Feedback Control of Robot-Assisted Needle Insertion: A Survey of the Literature," *Sensors*, vol. 18, no. 2, p. 561, Dec. 2018.

[12] N. Abolhassani, R. Patel, and M. Moallem, "Needle insertion into soft tissue: A survey," *Medical Engineering & Physics*, vol. 29, no. 4, pp. 413–431, Aug. 2006.

[13] A. I. Chen, M. L. Balter, M. I. Chen, D. Gross, S. K. Alam, T. J. Maguire, and M. L. Yarmush, "Multilayered tissue mimicking skin and vessel phantoms with tunable mechanical, optical, and acoustic properties," *Medical Physics*, vol. 43, no. 6, pp. 3117–3131, 2016.

[14] J. L. Kendall and J. P. Faragher, "Ultrasound-guided central venous access: a homemade phantom for simulation," *Cjem*, vol. 9, no. 05, pp. 371–373, Feb. 2007.

[15] D. L. Timms, "Design, Development and Evaluation of Centrifugal Ventricular Assist Device," B.S. thesis, Mechanical Eng., Queensland University of Technology., Brisbane., 2005.

[16] D. L. Woods, J. M. Wyma, E. W. Yund, T. J. Herron, and B. Reed, "Factors influencing the latency of simple reaction time," *Frontiers in Human Neuroscience*, vol. 9, 2015.

[17] P. Gandhi, P. Gokhale, H. Mehta, and C. Shah, "A comparative study of simple auditory reaction time in blind (congenitally) and sighted subjects," *Indian Journal of Psychological Medicine*, vol. 35, no. 3, p. 273, 2013.