Early Detection of Edema due to Diabetic Nephropathy

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***Abstract*—Diabetic Nephropathy can occur within the first 5 years since the onset of Diabetes Mellitus and can lead to severe issues such as amputations, heart failure, loss of sight and increased cardiovascular mortality [1,2]. Therefore, we have created a system to detect edema as an early warning system placed within the lip of the shoe. This will allow physicians to monitor the buildup of edema that patients with Diabetic Nephropathy are experiencing. Thus allowing them to make the best judgments in regards to the development of the nephropathy as to when to begin certain treatments like dialysis. This system will monitor the degree of edema buildup in the foot through the use of strain gauges which will allow us to monitor the pressure in the foot after calibration.**

I. Introduction

Diabetes Mellitus can be classified into two main groups: Type I and Type II diabetes. Type I diabetes classifies cases with β-cell destruction and absolute insulin deficiency, whereas Type II classifies cases where the is a progressive loss of β-cell insulin secretion, and insulin insensitivity [3]. Diabetic Nephropathy (DN) is exhibited by glomerular lesions and the progressive deterioration of the glomerulus in the nephron [1]. This can lead to more severe downstream effects such as loss of vision, amputation due to necrotizing fasciitis, or even increased cardiovascular mortality [1,2,4]. While typically the first sign of deterioration comes from the presence of albumin in the urine, peripheral edema is the first symptom of DN [5].

This buildup of edema stems directly from the degradation of the glomerulus in the kidneys and subsequently the glycocalyx in the capillaries[6,7,8]. The fluid exchange system in the capillaries is governed by the Starling equation and relies on hydrophilic molecules such as albumin to remain within the venous system. Thus due to the breakdown and subsequent ineffectiveness of the glycocalyx in the capillaries plasma proteins like that of the globular albumin are able to seep into the interstitial space.

The glycocalyx typically would prevent larger hydrophilic plasma proteins from escaping the capillaries and as such serve to balance the oncotic forces between the interstitial and intervascular spaces. This pressure change and the resultant net flux that it imposes are reflected by the Starling equation which is used to calculate the net flux between the arteriole and venous ends of capillary beds. From this equation, we have the Stavemen's reflection coefficient(σ) which denotes the efficiency of the glycocalyx in filtering out albumin from the interstitial space[6]. In the Starling Equation, π represents the oncotic pressure and P is the hydrostatic pressure. In both cases, it is intervascular minus interstitial pressure [6,7,8].

$$J_v = L_p S([P_c - P_i] - \sigma[\pi_p - \pi_i]) \tag{1}$$

In patients experiencing pulmonary edema $\sigma < 1$ due to the lowered effectiveness of the glycocalyx. This in turn results in a net flux outward from the capillary beds. Such that patients experiencing pulmonary edema had an interstitial oncotic pressure of 5mmHg, while healthy patients had an oncotic pressure of -1mmHg [2]. This oncotic pressure is what our device aims to detect and from this, we can deduce the degree of edema.

II. Methods

A. Proposed Solution

In order to detect the development of edema early on, foot swelling should be monitored. To track the swelling of the foot, we suggest designing a shoe that can measure the pressure inside. This will be done using an array of linear strain gauges all over the tongue of the shoe (the flap of the shoe under the laces). These strain gauges will be used to create a pressure field on the top of the foot while it is in the shoe. The other aspect of the design is adding another strain gauge attached to an LED so that if the pressure in the shoe reaches a certain threshold set by the patient's doctor, the shoe will light up.

B. Assumptions

When creating the circuits, it is assumed that all components are ideal. The resistance in the wire is assumed to be zero and that the current coming into all of the operational amplifiers is zero. In the calculations, it is assumed that the resistors are exactly the resistance that they are supposed to be. In reality, none of these assumptions are true, but it will not significantly impact the results or design of the circuit.

C. Strain Gauge Array for Creating a Pressure Field

The circuit will be hooked up to a voltage source of 3V. The voltage source is attached to a resistor that will be attached to a linear strain gauge. This setup was chosen instead of something like a wheatstone bridge because it uses fewer parts and less energy. Therefore this design is more efficient and more cost effective than a wheatstone bridge. The resistor will have a resistance of 500 kΩ and the resistance of the strain gauge will vary with pressure.

At the node between the strain gauge and the resistor, a buffer is added to separate the strain gauge from the rest of the circuit. The buffer is an operational amplifier with negative feedback that will ensure that voltage coming into the buffer is equal to voltage coming out of the buffer.

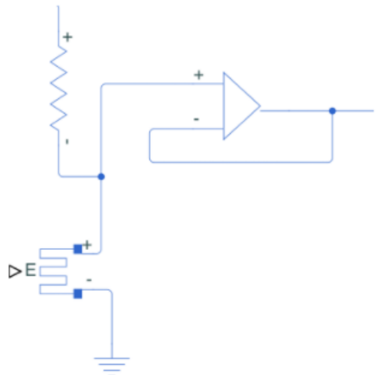

Fig. 1. Diagram of the strain gauge and buffer that is used to transduce pressure into voltage.

After the buffer, a high pass filter is attached. A high pass filter consists of a capacitor and a resistor which is connected to ground. The purpose of the filter is to shift the voltage coming out of the buffer to be centered around zero, eliminating the DC offset. The value of the capacitor is 10^{-6} F and the value of the resistor is $2\pi \cdot 10^{-5}\Omega$. These values were chosen to create a low cutoff frequency so as to not filter out any of the desired signals.

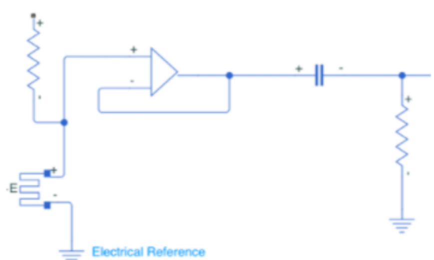

Fig. 2. Adding a high pass filter onto Figure 1.

Finally, the circuit is connected to a microcontroller. The microcontroller will be used to transduce the voltage reading coming in to a pressure reading. More specifically, at least during the prototyping phase, an Arduino Nano will be used as the microcontroller. The controller will send the pressure data to an app for both the doctor and the patient to view.

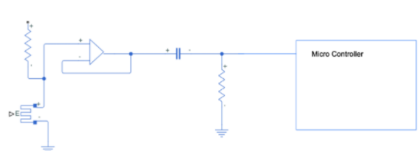

Fig. 3. Diagram of the circuit for creating the pressure field in the tongue of the shoe

D. Arduino

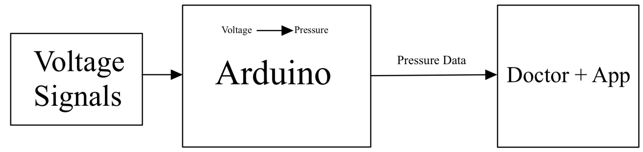

Fig. 4. Voltage processing flow diagram for Arduino.

An Arduino Nano takes in voltages that were passed into it from the strain gauge array built into the shoe. Each voltage coming into the Arduino Nano is converted into a corresponding pressure reading. These pressures are then relayed to the user's doctor and the user's phone app. It should be noted that the Arduino must be calibrated by the doctor before initial use in order to read pressure accurately.

E. Strain Gauge to LED Circuit

The circuit described in this section measures the pressure felt in the shoe and if it reaches above a certain threshold, an LED in the shoe will light up alerting the patient that something might be wrong.

The first half of the circuit is the same as the circuit described in section C of Methods. It consists of a resistor and strain gauge to transduce pressure into voltage. The voltage will go through a buffer to isolate the strain gauge from the rest of the circuit to prevent any malfunctioning. Then a high pass filter is connected to get rid of the DC offset. The values of the components will be the same as in section C of the Methods, see Figure 2.

Instead of being hooked up to a microcontroller, it is hooked up to a comparator. A comparator works using positive feedback, driving the voltage high or low depending on the voltage coming in. The voltage thresholds are set by the resistors connected to the comparator. The comparator in this circuit will have the top resistor with a value that can range based on what the maximum pressure the doctor concludes is dangerous and the bottom resistor will have the value 1 kΩ. This makes the voltage thresholds variable depending on the patient. When the voltage goes above the top threshold, the voltage will jump up to 3 V, the supply voltage. When the voltage reaches the lower threshold, the voltage jumps down to 0V.

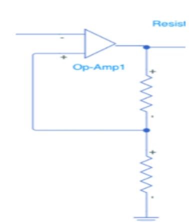

Fig. 5. The comparator hooked up to the rest of the circuit displayed in Figure 2.

After the comparator, an astable 555 timer is attached. The value of the capacitor connected to the CONT terminal will have a value of 10 nF. The other capacitor will have a value of 1 μF and the resistor will have a value of 721 Ω. This will cause the frequency of the voltage output to be 1000 Hz. This will serve to turn a constant high voltage coming in from the comparator to an oscillating voltage coming out of the timer.

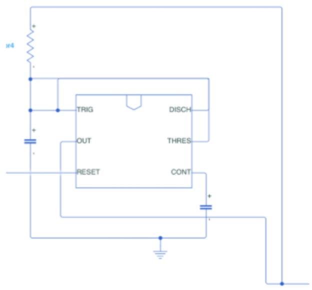

Fig. 6. Circuit diagram of the 555 timer that will be hooked up to the comparator.

Finally, the voltage will go through an LED diode. The quickly oscillating voltage created when the pressure experienced in the shoe is too high, the LED will quickly flash on and off alerting the patient that something may be wrong. As soon as the pressure decreases below the threshold, the LED will turn off.

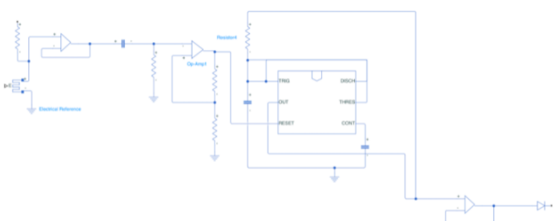

Fig. 7. Full circuit diagram of the LED circuit used for immediate detection concerning pressure levels.

III. Results

In order to test to see whether or not these circuits work, simulations need to be run. The first simulation done was to test the effectiveness of the LED circuit displayed in Figure 7. The simulation was done on the website Falstad. The circuit diagram put into this software is shown below in Figure 8.

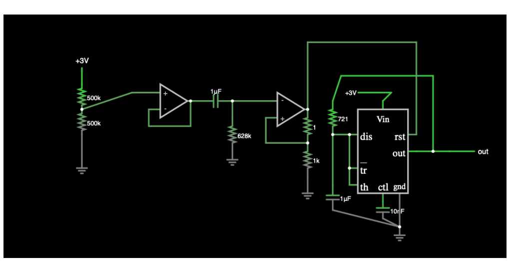

Fig. 8. The circuit diagram of the LED circuit in the simulation software Falstad. The LED that is attached to the circuit is not shown. Instead of the LED, the voltage is being measured where the LED would be. It should be noted that the value of the strain gauge is 500 kΩ, indicating high levels of pressure. The value of the second resistor in the comparator was set to 1 kΩ.

The results of the simulation are shown below.

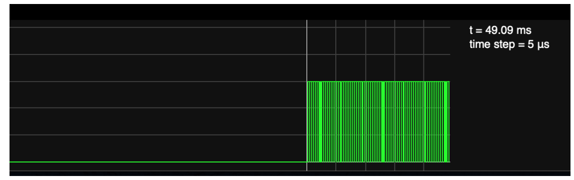

Fig. 9. The circuit diagram of the LED circuit in the simulation software Falstad. The LED that is attached to the circuit is not shown. Instead of the LED, the voltage is being measured where the LED would be. It should be noted that the value of the strain gauge is 500 kΩ, indicating high levels of pressure. The value of the second resistor in the comparator was set to 1 kΩ.

Since the strain in this simulation is high, it causes the comparator to go to its upper limit. Since the upper limit of voltage goes into the 555 timer, it will create an oscillating voltage like the one shown in Figure 9.

Another simulation was done in order to look at the circuit's response to lower levels of pressure. This time, the resistance of the strain gauge was set to 100 kΩ. With a low pressure reading, the voltage stays at zero.

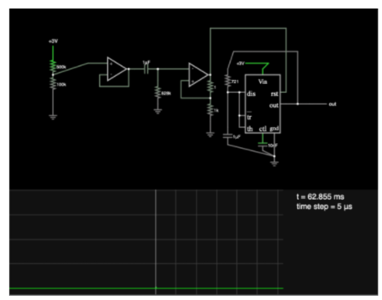

Fig. 10. Simulation for a lower strain with the strain gauge set to 100 kΩ. It can be seen that the voltage from the output stays at zero.

Another simulation was done for the circuit that would be an array of strain gauges feeding voltage readings to the microcontroller.

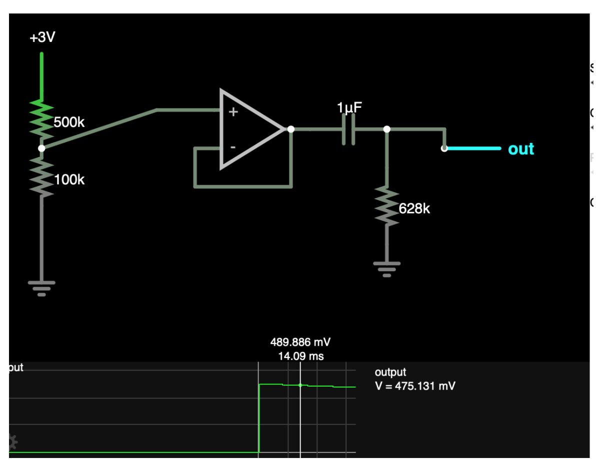

Fig. 11. In this circuit diagram, the strain gauge was set to low resistance to simulate a low-pressure reading. This caused an output voltage of around 500 mV.

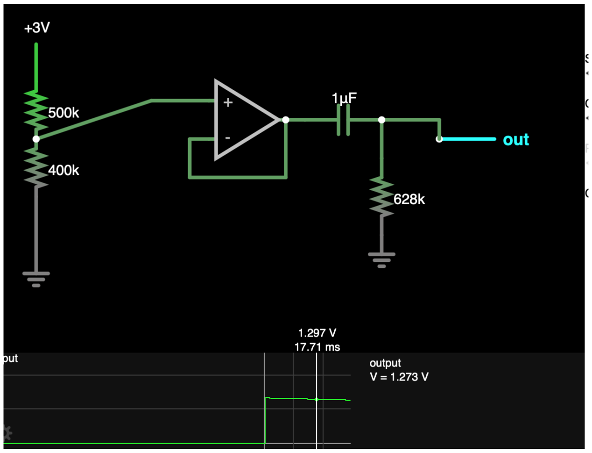

Fig. 12. In this circuit diagram, the strain gauge was set to a higher resistance to simulate a higher pressure reading. This caused an output voltage of around 1.3 V.

From the simulations above, it can be seen that with a higher pressure reading, the higher the voltage coming into the microcontroller. This is exactly how we want the circuit to behave so that the microcontroller can transduce the voltage readings into pressure readings.

IV. Discussion

This device can be an effective early indicator of edema in patients with DN. In theory, this design should work well, but it is impossible to know for sure without testing.

In the future, after the design has gone through its prototyping phase, it is important to conduct clinical trials. Through these trials, the design of the shoe can be tweaked based on feedback from the patients who are testing them. If the patients say that the shoes are too bulky or uncomfortable, the shoe must be redesigned. Comfort and wearability are extremely important factors because the shoes are meant to be worn as much as possible so that large amounts of data spanning a long period of time can be collected. Having lots of data is important to monitor the development of edema over time. Also, having data spanning the whole day is beneficial to see if any issues of high pressure resolve themselves throughout the day.

One issue that comes with so much data is that there is a lot of variability in pressure throughout the day. Putting on the shoes and taking them off will cause spikes in pressure. Walking will also cause the pressure to oscillate. In addition, there are random occurrences that might cause a temporary spike in pressure that may have nothing to do with edema. It will be more difficult for doctors to analyze the data since there can be a lot of normal variability, however, this will not prevent the detection of long-term pressure build-up. In an ideal world, this device would be used to measure pressure while the patient stands still for a long period of time. This method of data collection would lead to data that is easier to analyze but is much less convenient for the patient. Therefore the method of gathering as much data as possible through having the patient wear the shoes all day was deemed more beneficial than gathering data that is easier to analyze.

In the future, tests should be conducted to determine the optimal amount of strain gauge circuits in the shoe in order to get enough information. Further testing also needs to go into how the doctors should pick the optimal value for the second resistance in the comparator. Also, since this is just a prototype design, it was decided to use an Arduino Nano as a microcontroller. In the future, it will be beneficial to look into other types of microcontrollers.

V. Conclusion

In conclusion, because the output voltage responds to low pressure and high pressure differently, it can be used to differentiate between what is considered normal pressure exerted by the feet and abnormal pressure exerted by the feet. Due to this ability, we believe it would be excellent for detecting edema in the feet, an early sign of DN, and end-stage renal failure. Through prototyping and real-world testing and trials, this can become a viable product that can be used to help prevent further advancement of DN and renal failure. Hopefully, with this in mind, the product could prevent countless deaths and ensure that patients are getting the treatment they need.

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