Jurnal Ilmiah Teknik Elektro Komputer dan Informatika (JITEKI)
Vol. 9, No. 4, December 2023, pp. 1080-1092
ISSN: 2338-3070, DOI: 10.26555/jiteki.v9i4.27152

Development of Simple Control System for a Negative Pressure Wound Therapy Device

Angga Davida[1], Basari[1,2]
[1]Biomedical Engineering Program, Department of Electrical Engineering, Faculty of Engineering, Universitas Indonesia, Depok, Indonesia
[2]Research Center for Biomedical Engineering, Faculty of Engineering, Universitas Indonesia

ARTICLE INFO

Article history:

Received September 07, 2023
Revised November 02, 2023
Published November 17, 2023

Keywords:

Arduino;
Control system;
Diabetic ulcer;
Negative pressure wound therapy;
PID controller

ABSTRACT

Diabetic ulcers are wounds found on the legs of diabetic patients. Improper treatment opens the risk of complications like sepsis and osteomyelitis. A notable method of treatment is through a Negative Pressure Wound Therapy (NPWT) device. This device helps ulcer recovery by removing exudate, increasing blood flow, and promoting cellular proliferation via negative pressure. The objective of this study is to increase the local content of an affordable and effective method of diabetic ulcer therapy by developing a simple, low-cost NPWT prototype. This was achieved by using an Arduino UNO microcontroller, which included PID controls, an MPXV4115VC6U sensor reading function, an in-built timer, two modes, and an alarm system. The resulting prototype was calibrated before testing to reduce error rates. Testing was conducted using a Gas Flow Analyzer and an ulcer wound phantom. Negative pressure settings of 75, 85, and 125 mmHg were used for testing and were conducted on both modes for 30 minutes each. From these tests, it was found that the prototype could reach the negative pressure thresholds with minimal average error of at most -1.81%. With a wound phantom, the average error was -0.56% and -0.20% for the continuous and intermittent modes respectively. This small variance is negligible because NPWT therapy has a wide range of acceptable negative pressure, namely 60-80 mmHg and 80-125 mmHg, depending on wound type. In conclusion, a simple Arduino UNO-based system can function as an NPWT therapy device to aid diabetic ulcer recovery with minimal error.

Corresponding Author:

Basari, Universitas Indonesia, Kampus UI Depok, Depok 16424, West Java, Indonesia
Email: basari.st@ui.ac.id

1. INTRODUCTION

Diabetes mellitus is a disorder of the endocrine system that disturbs the functions of insulin, leading to hyperglycemia [1]. A majority of diabetes cases can be attributed to 2 types [2]: type 1, which is caused by a decrease of pancreatic β-cells, and type 2, which is caused by increased cellular resistance towards insulin accompanied by mild loss of pancreatic β-cells [1], [3]–[6]. It is projected that by 2040, about 10.4% of people ages 20-79 all over the world will have diabetes [7].

A diabetic ulcer is a wound usually present in the foot of diabetic patients, caused by a combination of pathophysiological factors (diabetic neuropathy, ischemia, neuropathy) and environmental factors (foot traumas and mechanical pressure) [8]–[10]. The lifetime risk of a diabetic patient developing such wounds is 15% [11]. Improper treatment of diabetic ulcers over time may lead to further complications, such as cellulitis, sepsis, osteomyelitis, gangrene, and pathogenic infection, leading to the need for amputation [12]–[16]. Proper diabetic ulcer treatment requires starting with debridement, which is the removal of foreign debris and necrotic tissue in and around the wound area using nonmechanical and mechanical methods [17]–[19]. Afterward, the infected foot needs to be relieved of pressure as much as possible, which is usually done through Total Contact

Casting (TCC) [20], [21]. In addition to these methods, treatment can also be done by applying negative pressure to the wound area through a Negative Pressure Wound Therapy device [22].

Negative Pressure Wound Therapy (NPWT) is a non-invasive therapeutic device used to promote the healing of acute and chronic wounds [11], [22]–[27], and is especially effective in treating diabetic foot ulcers compared to conventional dressings [28]. It consists of a negative pressure pump, a canister to contain wound exudate, and a dressing to fill the wound cavity [22], [28]. The negative pressure applied by NPWT can promote the creation of a granulation layer, increase blood flow, and increase cellular proliferation, while also helping to remove pathogens and other waste from the wound area when used in conjunction with other therapeutic methods such as UV light therapy [22], [23], [28]–[32]. The amount of negative pressure applied depends on the type of wound. For example, ulcers with vascular lesions should be treated with 60-80 mmHg of negative pressure, while ulcers without vascular lesions should be treated with 80-125 mmHg of negative pressure [33]. There are two negative pressure application modes, namely continuous and intermittent [22], [34], [35]. Continuous therapy is done by applying negative pressure consistently throughout therapy, whereas intermittent therapy uses short, typically 2-minute breaks in between negative pressure applications [29]. Intermittent therapy is more favorable due to the short breaks significantly improving blood flow [29], as well as hastening cellular regeneration due to mechanical stimulation from the alternating pressure. Despite these improvements, patients have reported intermittent therapy to be more painful than continuous therapy due to the mechanical stimulation [36], and as such must be used with patient consent.

Despite NPWT devices being commercially available, they are known to be costly [37]. Therefore, low-cost efforts are taken to help provide more affordable wound therapy for most hospitals in regions with low or middle-income countries. One such way is through replacing a component, such as by replacing the canister with a cheaper one [38]. A notable drawback of this method is that it is considered an off-label use, which might alter the intended function of the original design. Another study presented a cheaper, modified NPWT system [39]. With a negative pressure output of 450 mmHg, it also uses medical gauze as opposed to solid foam, which helps with wound monitoring. Notable drawbacks of this research are that the developed device is incapable of manipulating its applied pressure for intermittent therapy and that the explanation regarding the full modifications done in the research is lacking.

Another low-cost NPWT device has been developed [40]. It can output 25-175 mmHg of negative pressure and it has a built-in alarm system that prevents an output higher than 200 mmHg or lower than 15 mmHg of negative pressure. A limitation in the design, however, is the lack of an alarm system that can automatically pause the device if the applied negative pressure is outside of its designated range, preventing the device from operating in the case of pump blockage or malfunction.

The contribution of this research is to increase the local content of affordable diabetic ulcer therapy by developing a simple, low-cost NPWT device. In a broader perspective, this research provides a stepping point for future studies regarding affordable diabetic ulcer therapy via negative pressure application.

2. METHODS

This research focuses on the development of software to control an NPWT prototype. Fig. 1 shows the diagram of the methodology used in this study. Starting from designing a diagram as an outline for the control system, it was then converted into code to be executed by an Arduino UNO R3 microcontroller using Arduino IDE. The sensor, timer, and PID function of the prototype are then calibrated using standard measurement devices. The last step of this research was measuring the prototype's performance using a Gas Flow Analyzer VT650 from Fluke Biomedical™ in a controlled setting, measuring performance using a wound phantom, and data analysis.

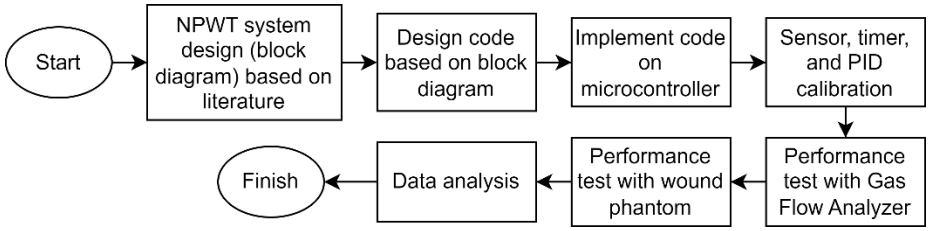

Fig. 1. Research methodology diagram.

The electrical components used to fabricate the prototype used in this research were an Arduino UNO R3 microcontroller, an L298N motor driver, a 5V DC negative pressure pump, an AC to DC adapter, a 16×02 LCD with its I2C module, a 5V buzzer, an LED, and push buttons. The pressure sensor used in this study is

the MPXV4115VC6U pressure sensor. An exudate canister and silicone tube were also used as supplementary materials.

2.1. Block Diagram

Fig. 2 shows a block diagram that illustrates interactions between the electrical components used in the finalized prototype, as well as the prototype itself.

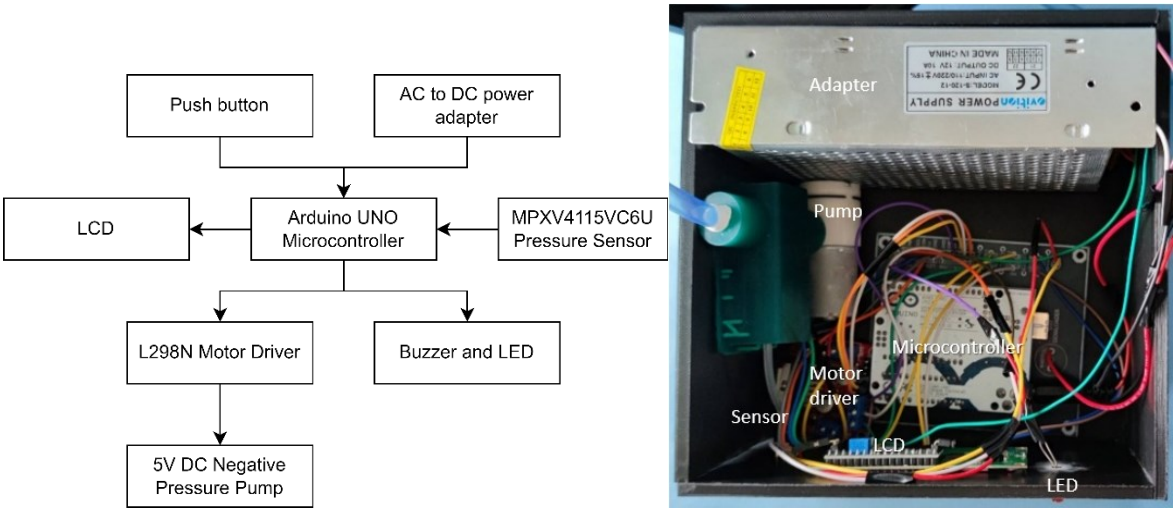

Fig. 2. Block diagram of the NPWT circuit prototype (left). The circuit configuration of the finalized prototype inside of its casing (right).

A detailed description for each block shown in Fig. 2 is presented.

1. Push Buttons
   Push buttons are used to relay information from the user to the microcontroller.
2. LCD
   The LCD relays information from the microcontroller back to the user.
3. L298N Motor Driver
   The motor driver functions to convert PWM signals transmitted by the microcontroller into various levels of voltage, enabling easier implementation of pump speed controls.
4. Negative Pressure Pump
   The pump functions as the effector of this device, which outputs negative pressure.
5. MPXV4115VC6U Pressure Sensor
   The pressure sensor obtains and relays real-time information on negative pressure produced by the pump, which functions as feedback for a closed-loop control system.
6. Buzzer and LED
   The buzzer and LED are used to help indicate faulty performance to the user via noise and light.
7. Arduino UNO Microcontroller
   The microcontroller is used to obtain information from the user, turn the pump on or off, and calculate the appropriate speed needed for the pump to stabilize its output via a closed-loop control system.
8. AC to DC Adapter
   The adapter is used to convert AC voltage into DC, which is used by all electrical components in this prototype.

2.2. Electric Component and Casing Design

A 3-dimensional (3D) model of the NPWT prototype casing and the placement of every electrical component are made in Autodesk Inventor and is shown in Fig. 3**.** From Fig. 3, it is shown that the circuit of this prototype was designed to be able to fit inside a block-shaped casing as compactly as possible to minimize complexity and ease experimentation. Additionally, most of the cables used in this prototype were jumper cables, so any malfunctions occurring during experimentation can be swiftly repaired, via disassembly and reassembly. The casing is a simple block 3D printed using PLA as its material that has a removable top cover for easy inspection of its inner circuitry.

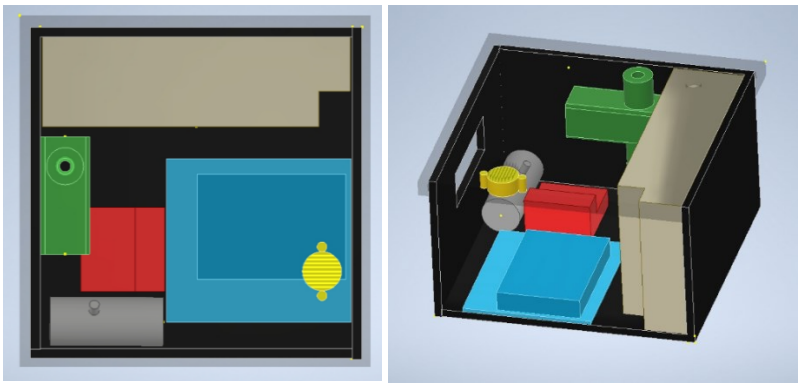

Fig. 3. 3D model of the NPWT prototype: top view (left) and perspective view (right).

2.3. Flowchart of NPWT workflow

Two flowcharts have been made to show the prototype's mechanisms. Fig. 4 explains the pump control system, while Fig. 5 explains the logic system of the alarm function.

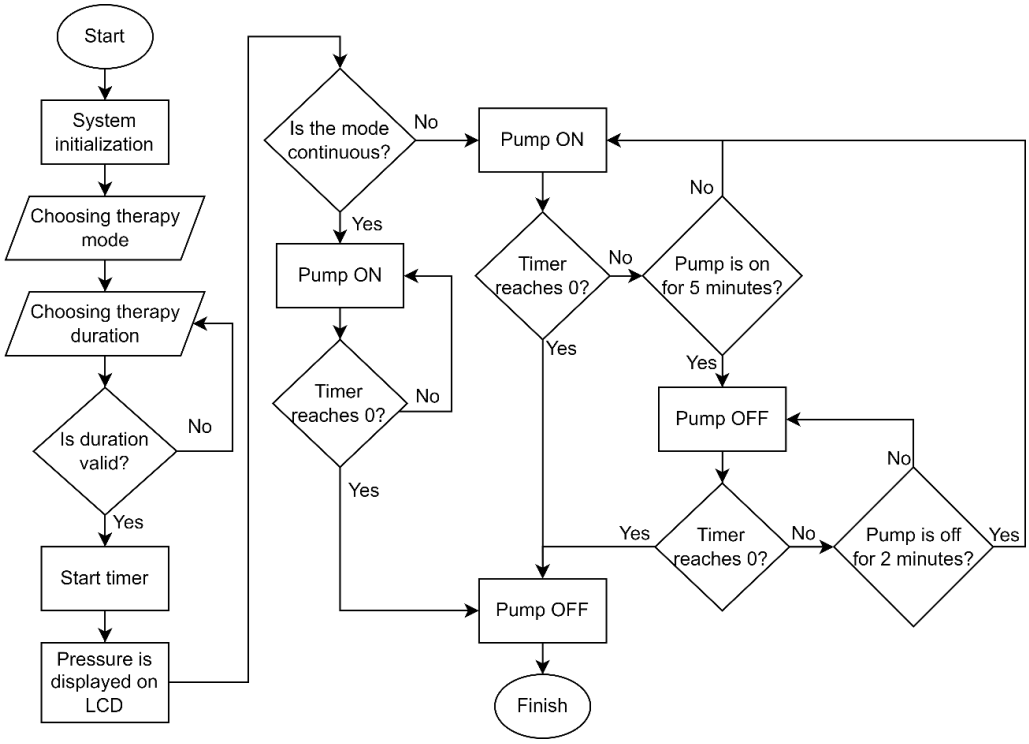

Fig. 4. Block diagram of the NPWT prototype.

Fig. 4 shows that the pump is controlled based on the chosen therapy mode and the pressure sensor feedback. In continuous mode, the pump will only be controlled based on pressure sensor feedback, but in intermittent mode, the pump will be forcibly turned off at intervals regardless of pressure sensor feedback. After 5 minutes of operating, the pump will then be turned off for 2 minutes, as is typical in NPWT device operation [29].

Fig. 5 shows the function of two variables used in the logic of the alarm function, namely *majorleak_s* and *minorleak_s*. *Minorleak_s* is used to contain the amount of time elapsed since the first detection of minor leakage, while *majorleak_s* is used to contain the amount of time elapsed since the first detection of major leakage. When 10 seconds have been contained in either *minorleak_s* or *majorleak_s*, the system will display an exclamation mark ("!") on the LCD, indicating that an error may be present to the user. After 2 minutes has been contained in *minorleak_s*, or after 1 minute has been contained in *majorleak_s*, the alarm function will activate, disabling the pump's activity while also showing "ERROR" on the LCD and flickering both the LED and buzzer.

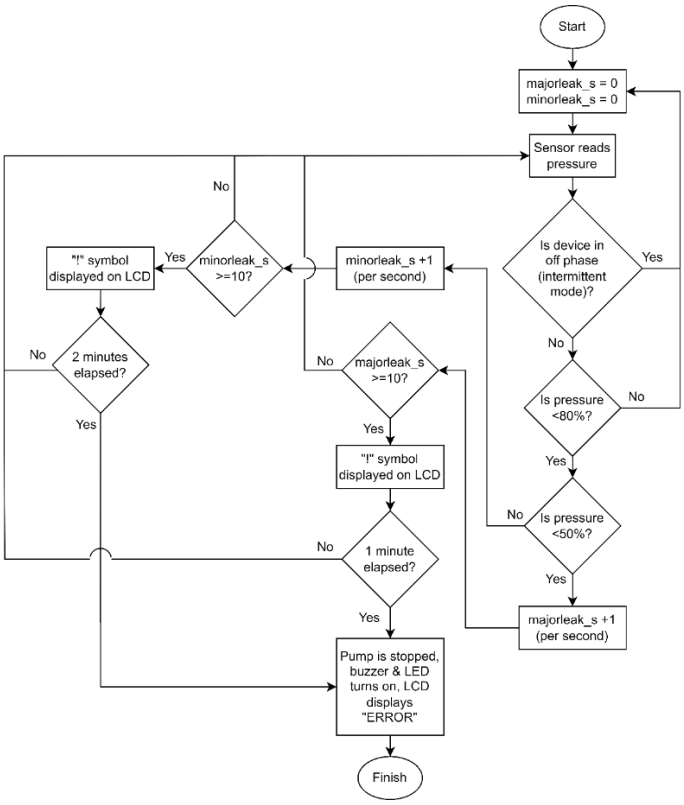

Fig. 5. Block diagram of the alarm function.

2.4. Timer Calibration

The timer function in the fabricated prototype uses the internal clock already present in Arduino UNO R3, by increasing the timer variable *t* by 1 for every 1000 ticks. Because of this, the timer function did not have high innate accuracy, and it required calibration by error compensation. Initial data gathering of the timer's error rate was done by running the prototype and comparing its calculated time against a standard, namely the timestamp feature in Arduino IDE. Equation (1) is used to obtain the error number for each second counted by the timer:

$$t_{N.e} = t_N - t_{N.npwt} \tag{1}$$

where $t_{N.e}$ is the error for the nth second, t_N is the nth second from the Arduino IDE timestamp, and $t_{N.npwt}$ is the time calculated by the timer system for the nth second. From the total accumulated error over a certain number of seconds, arbitrarily chosen to be 20 seconds ($\sum_{20} t_{N.e}$), an acceleration function is implemented that skips the tick count by that same amount. From there, another data-gathering session was conducted to see the average error rate of the timer post-calibration.

2.5. Pressure Sensor Calibration

The MPXV4115VC6U pressure sensor detects negative pressure inside of the NPWT prototype's silicon tubing and relays this information into the microcontroller in the form of a voltage signal between 0-5V. The microcontroller then converts this signal into a unit of pressure using the sensor's transfer function as stated on its datasheet, which is defined as follows:

$$Vo = Vs \times \left((0.007652P) + 0.92\right) \pm error \tag{2}$$

with Vo as the sensor's output voltage, Vs as the sensor's input voltage, and P as the detected pressure in kPa. Therefore, to obtain P, (2) is then modified as follows:

$$P = \frac{Vo + 0.92\,Vs}{0.007652\,Vs} \tag{3}$$

with Vs used in this prototype being 5V. Because Arduino UNO R3 reads the pressure sensor's output as a digital unit between 0-1023 proportional to the sensor's maximum output, which is 5V, a formula to convert

the analog Vo into a digital form is needed. The conversion as well as the currently used Vs were added into (3) as follows:

$$P = \frac{(\frac{5}{1023}) + 0.46}{0.03826} \tag{4}$$

Lastly, to convert the result into mmHg, the kPa to mmHg conversion method was also included. Therefore, the transfer function used in the prototype's system is as follows:

$$P(mmHg) = \left(\frac{\left(\frac{5}{1023}\right) + 0.46}{0.03826} \times -7.5 \right) \pm error \tag{5}$$

Calibration was used to find the appropriate error constant of the pressure sensor. This was conducted by averaging the sensor's error rate after measuring negative pressure at different, randomized points alongside the Fluke Biomedical™ VT650 gas flow analyzer (GFA) as the standard. This averaged error rate was then plugged back into (5), creating the complete transfer function used in this prototype. The prototype was then tested with the same method to verify whether its error rate had decreased.

2.6. PID Controller

The system used to stabilize the negative pressure pump's output level according to the MPXV4115VC6U pressure sensor's feedback is a PID (proportional, integral, derivative) control system. Equation (6) shows the PID formula used in this prototype.

$$s(t) = K_p a(t) + K_i \sum_{i=0}^{t} a(i) + K_d\big(a(t) - a(t-1)\big) \tag{6}$$

where $s(t)$, which is between 0-255, is the pump's speed at time t. $a(t)$ is the error between current pressure and desired pressure at time t, $a(t-1)$ is the error between current pressure and desired pressure at a time before t, and K_p, K_i, K_d are the constants for proportional, integral, and derivative calculations respectively. Through the trial-and-error method, it was found that for this prototype, $K_p = 3.0, K_i = 0.7, K_d = 0.08$.

To prevent saturation, which is the phenomenon where the microcontroller sends an input signal commanding the pump to accelerate or decelerate at a speed above the pump's realistic capabilities, the PID system is given a clamping countermeasure. Clamping will prevent the PID output from reaching a value above or below the pump's power and prevent integral windup by temporarily multiplying the integral part of the equation by 0. In this prototype, clamping is done when $0 \leq s(t) \leq 80$.

2.7. Prototype Testing

Testing of the prototype was done by using a Gas Flow Analyzer and then a wound phantom. In the Gas Flow Analyzer test, the silicon tube of the prototype was directly connected to an input knob of the analyzer. The prototype was then turned on in a variation of settings, namely 75, 85, and 125 mmHg for both continuous and intermittent therapy modes for 30 minutes. The same test was done with a wound phantom. The phantom's wound area was covered with Hypafix gauze and its cavity was filled with wound dressing before inserting the prototype's silicon tube.

Lastly, the implemented alarm function was also tested. The prototype was run with the setting 85 mmHg in continuous mode, and its output pressure was artificially reduced by controlled leakage to produce 2 different cases of leakage, a minor leakage (50% ≤ output pressure ≤80%) and a major leakage (output pressure < 50%). The time it took for the prototype from recognition of leakage to complete shutdown was calculated and verified against the intended time (2 minutes for minor leakage and 1 minute for major leakage).

2.8. Data Analysis

The resulting data from prototype testing were graphed to visualize the prototype's accuracy and stability in reaching and maintaining constant negative pressure. In the case of intermittent therapy, the time taken to transition from an on-phase to an off-phase was also measured. A total of 1800 data points were gathered from each instance of the test, with each data corresponding to 1 real-time second.

The amount of negative pressure detected by both the MPXV4115VC6U sensor and the Fluke Biomedical™ Gas Flow Analyzer were averaged by the amount of time the prototype was active (omitting the off-phase of intermittent mode), resulting in the average pressure applied by the prototype as detected by each

sensor. The difference between this number and the target pressure (indicated by the pressure setting) is the error rate of the prototype's performance.

3. RESULTS AND DISCUSSION

The specification of the fabricated prototype is presented in Table 1. The total retail cost of all materials used in the prototype was 1.096.120 IDR (about 68.81 USD). The minimum and maximum pressure settings were gathered from the acceptable range for negative pressure application to diabetic ulcers which is 60-125 mmHg [33]. The maximum duration of 4+ days was chosen since conventional NPWT treatment requires changing wound dressing every 3-5 days [33], aligning the prototype's function with conventional wound care. The alarm system has a grace period of 1-2 minutes before its emergency stop system to let time for users to notice the alarm system. Afterward, to save energy and prevent mistreatment, the emergency stop system will activate and terminate negative pressure application to the wound.

Table 1. Prototype specifications

Parameter	Specification
Minimum and maximum pressure	-75 mmHg to -125 mmHg
Maximum duration	99 hours 59 seconds (4+ days)
Alarm	Minor leakage 2 minutes, major leakage 1 minute
Tube material	Silicon
Casing material	PLA
Available therapy modes	Continuous and Intermittent

3.1. Timer Calibration and Testing

The time data gathered from the first 20 seconds of measurement is presented in Table 2. The data displayed in Table 2 shows that the 20 seconds calculated by the NPWT prototype is slower than real-time seconds by 0.632. To counteract this inaccuracy, a built-in function was implemented which accelerates the prototype's timer function by 632 ticks for every 19000 ticks/19 seconds.

Table 2. Timer data of the prototype pre-calibration.

NPWT system timer	Arduino IDE timestamp	Error	Error percentage
0	0	0	0%
1	1.032	-0.032	-3.20%
2	2.063	-0.063	-3.15%
3	3.094	-0.094	-3.13%
4	4.127	-0.127	-3.17%
5	5.159	-0.159	-3.18%
6	6.190	-0.190	-3.16%
7	7.223	-0.223	-3.18%
8	8.254	-0.254	-3.17%
9	9.286	-0.286	-3.17%
10	10.318	-0.318	-3.18%
11	11.349	-0.349	-3.17%
12	12.381	-0.381	-3.17%
13	13.412	-0.412	-3.16%
14	14.443	-0.443	-3.16%
15	15.474	-0.474	-3.16%
16	16.505	-0.505	-3.15%
17	17.536	-0.536	-3.15%
18	18.568	-0.568	-3.15%
19	19.599	-0.599	-3.15%
20	20.632	-0.632	-3.16%

After calibration, the prototype was tested again for 30 minutes. The resulting data from post-calibration testing was converted into a graph which is shown in Fig. 6, with each point being the average timer error per minute of activation.

Fig. 6 shows that the error of the timer function post-calibration is significantly smaller than pre-calibration, with an average error of 0.05% per minute. Despite having a linearly upward trend for the 1st to 20th minutes due to the instability of Arduino's internal clock, it is shown that the error average plateaus from the 21st minute onwards. In general, because the average duration of NPWT therapy is within the span of

several hours or days, an inaccuracy of 1-2 seconds presumably does not have significant negative effects on the applied therapy.

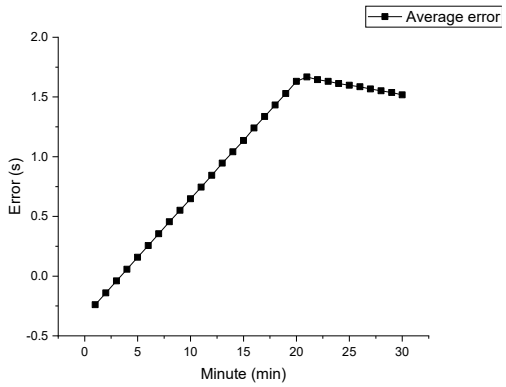

Fig. 6. Error per minute of the timer function post-calibration.

3.2. Calibration and Testing of MPXV4115VC6U Pressure Sensor

The sensor's output measurements and the gas flow analyzer's measurements are shown in Table 3. Based on the data in Table 3, it was discovered that the average negative pressure measurement error is +15.45. Therefore, this number was used as the error constant in (7).

Table 3. Negative pressure value from MPXV4115VC6U sensor and gas flow analyzer pre-calibration.

Sensor Value	Reference Value	Error
-18.76	0.00	18.76
-3.43	7.61	3.92
1.36	13.54	12.18
7.11	19.41	12.30
12.86	24.13	11.27
16.69	31.89	15.20
20.52	35.66	15.14
24.35	40.21	15.86
32.02	46.39	14.37
35.85	50.16	14.31
38.72	55.16	16.44
47.35	60.46	13.11
50.22	65.04	14.82
55.01	70.15	15.14
58.84	75.25	16.41
64.59	80.04	15.45
71.30	86.48	15.18
75.13	90.45	15.32
81.84	94.30	12.46
87.59	101.60	14.01
89.50	105.16	15.66
99.08	112.20	13.12
102.92	116.36	13.44
105.79	120.08	14.29
107.71	123.37	15.66
	Average	15.45

$$P(mmHg) = \left(\frac{\left(\frac{5}{1023}\right) + 0.46}{0.03826} \times -7.5 \right) + 15.45 \quad (7)$$

The complete transfer function (7) was then implemented into the microcontroller's program before redoing the pressure sensor test. The data from post-calibration testing is shown in Table 4.

Table 4 shows that the sensor's measurements post-calibration have a low error rate, averaging at about -0.54%. Notably, the sensor has difficulty reading low negative pressure, as shown by the 94.01% accuracy at reading around 29 mmHg. However, at 50-120 mmHg, its accuracy increases dramatically, reaching an

accuracy of 99.99%. Since the NPWT prototype's pressure settings do not reach below 50 mmHg, this dip in accuracy should not affect its performance.

Table 4. Negative pressure value from MPXV4115VC6U sensor and gas flow analyzer post-calibration.

Sensor Value	Standard Value	Error	Error Percentage
31.18	29.42	1.76	5.99%
41.72	41.86	-0.14	-0.33%
50.34	50.37	-0.02	-0.05%
64.71	64.62	0.09	0.13%
70.46	70.86	-0.40	-0.56%
81.96	82.02	-0.06	-0.08%
85.79	85.83	-0.04	-0.05%
91.54	92.55	-1.01	-1.09%
97.29	97.63	-0.34	-0.35%
100.16	100.13	0.03	0.03%
112.62	112.37	0.25	0.23%
116.45	116.52	-0.07	-0.06%
127.95	127.96	-0.01	-0.01%
	Average	-0.39	-0.54%

3.3. Negative Pressure Pump Testing

Performance evaluation of the pump was done by turning the prototype on for both continuous and intermittent modes for 30 minutes (1800 seconds) for the negative pressure settings 75, 85, and 125 mmHg. Fig. 7 shows the negative pressure graphs for all these setting combinations.

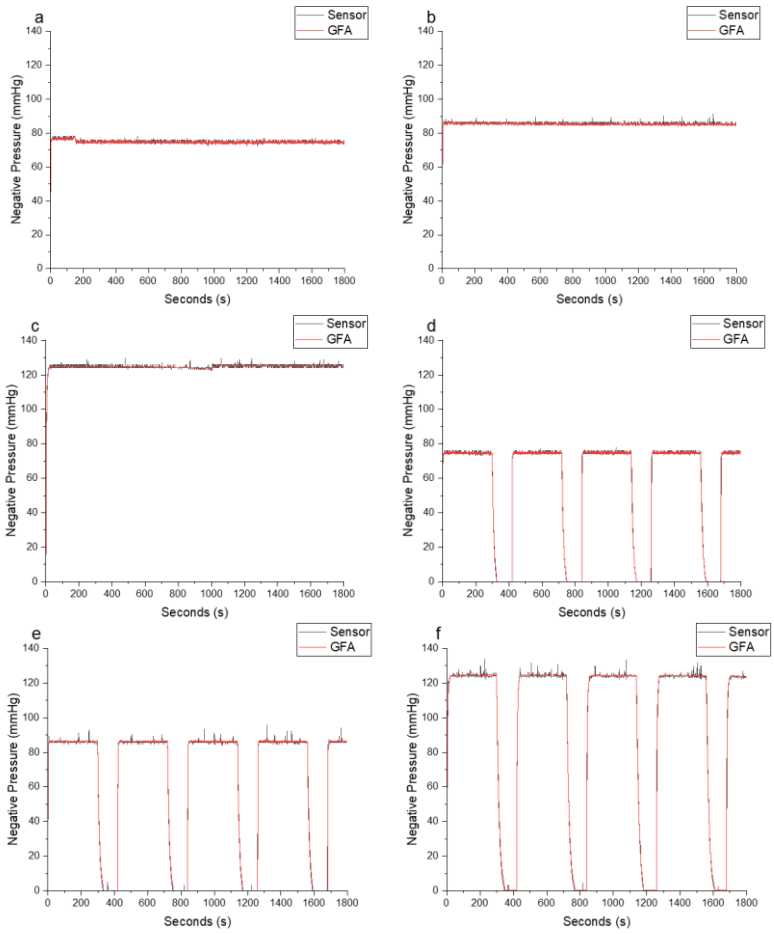

Fig. 6. Pressure output from the prototype for 30 minutes with the settings: a) 75 mmHg Continuous, b) 85 mmHg Continuous, c) 125 mmHg Continuous, d) 75 mmHg Intermittent, e) 85 mmHg Intermittent, f) 125 mmHg Intermittent.

The continuous therapy mode run by the prototype, as shown in Fig. 7(a), Fig. 7(b), and Fig. 7(c), exhibited a constant negative pressure output with errors within a small margin. Similarly, the performances of the intermittent therapy mode for all three pressure settings shown in Fig. 7(d), Fig. 7(e), and Fig. 7(f) show consistent negative pressure output appropriately spaced by off-phases 5 minutes apart. There is a small discrepancy between the average pressure detected by the MPXV4115VC6U pressure sensor and its standard, the Fluke Biomedical™ VT650 Gas Flow Analyzer. According to the pressure sensor, the average errors for each test, in order of 75, 85, and 125 mmHg, are -0.08%, 0.97%, and -0.16% for continuous therapy and -0.59%, 0.96%, and -1.81% for intermittent therapy. According to the gas flow analyzer, however, the average errors for each test in the same order are -0.22%, 0.43%, and -0.20% for continuous therapy and -0.59%, 0.96%, and -1.50% for intermittent therapy. The highest difference between these error rates is 0.50% apart, and despite this, both ultimately come to the same conclusion, which is that the pressure output can reach the intended target with minimal fluctuations.

3.4. Alarm Function Testing

Tests of the alarm function's performance were done by artificially reducing the pressure output of the negative pressure pump by steady leakage until it reached certain percentages of the target pressure, which was 85 mmHg in this case. For minor leakage testing, the pressure was lowered to 50% –80% of the target pressure, while for major leakage testing, the pressure was lowered below 50% of the target pressure. Graphs documenting the alarm's performance for both cases are presented in Fig. 8(a) and Fig. 8(b) respectively.

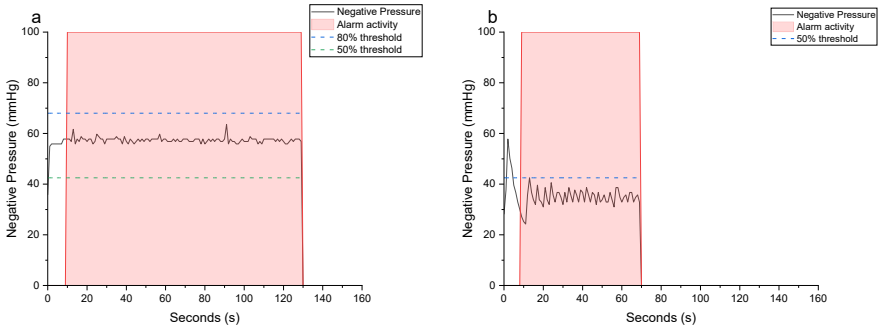

Fig. 7. Performance of the alarm system: a) Minor leakage, and b) major leakage.

Based on the graphs shown in Fig. 8(a) and Fig. 8(b), both major and minor leakage situations could be detected exactly 10 seconds after the inadequate pressure was first recorded. After 1 minute and 2 minutes for the major and minor leakage situations respectively, the alarm triggers and ceases all functions, giving an alert via buzzer and LED. This shows that the leakage alarm system is functional and works as intended.

3.5. Wound Phantom Testing

A short test using a wound phantom to simulate a diabetic ulcer wound, shown in Fig. 9(a), was done as illustrated by Fig. 9(b).

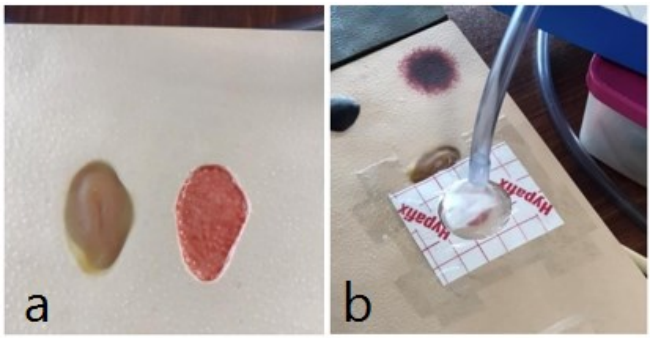

Fig. 8. Wound phantom testing: a) Wound phantom to simulate a diabetic ulcer. b) NPWT configuration on the wound phantom.

Fig. 9 shows the ulcer, which is about 2.5 cm in height and 0.2 cm in depth. A layer of Hypafix medical gauze was used to secure the silicone tubing unto the ulcer phantom, which was covered in wound dressing

beforehand. A negative pressure setting of 85 mmHg was used for this test, on both continuous and intermittent therapy modes. Graphs of these tests are shown in Fig. 10(a) and Fig. 10(b).

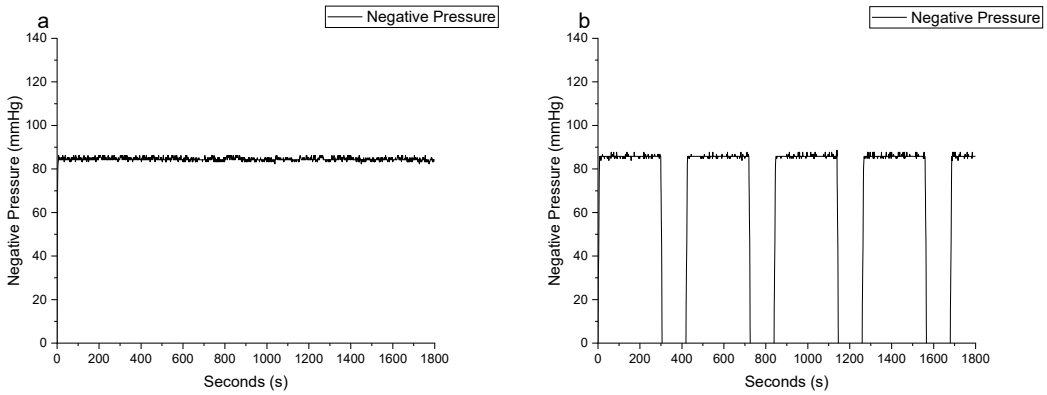

Fig. 9. Pressure output of the NPWT prototype, tested with a wound phantom at the settings: a) 85 mmHg continuous mode, and b) 85 mmHg intermittent mode.

From the two graphs shown in Fig. 10, it can be concluded that the prototype was able to operate smoothly on a wound phantom. An average negative pressure of 84.83 mmHg was applied on the wound phantom for both continuous and intermittent therapy modes, meaning a -0.20% error rate. This is in line with the results gathered from the controlled testing done with the Gas Flow Analyzer.

3.6. Discussion

The fabricated prototype has a controllable range of pressure output, namely from 75 to 125 mmHg, has a built-in timer system, as well as an alarm system that monitors leakage and terminates function if erroneous treatment continues. Additionally, it can perform both continuous therapy and intermittent therapy. In comparison, currently existing research [40] created an NPWT device with a wider range of pressure of 25 to 175 mmHg. However, advantages of the prototype created in this study are the implementation of a visual aid to the timer system, the addition of an auditory component on the alarm system to help garner user attention in case of emergencies, and an automatic stop that terminates performance if the alarms are ignored to prevent further mistreatment. The hypodermic needle present in the existing prototype is not used in this study, as the negative pressure pump used in this study can release negative pressure automatically if all its functions are ceased. Additionally, the fabricated prototype in this study is cheaper in production cost, being reduced by about 10%, which improves the reproduction feasibility of this prototype.

The main discovery and advantage of this study is the effectiveness of the prototype, being able to produce consistent and stable negative pressure that may compete with its commercial counterparts as proven by this study's testing. Moreover, it is vastly cheaper than commercial NPWT systems like VAC (491.38 USD), which is 7.14 times more expensive than this prototype [41]. Notable limitations of this study are that clinical trial has not been done using this prototype and that exudate flow simulation was not conducted in conjunction with wound phantom testing. Therefore, for further research and implementation of this prototype, it is imperative that additional testing is conducted to enable its usage in hospitals.

4. CONCLUSION

This paper outlines the design, fabrication, and performance analysis of a low-cost NPWT device prototype with an Arduino UNO R3 microcontroller. The prototype showed promise, being able to control pump speed with a PID system with error percentages of -0.08%, 0.97%, and -0.16% for the continuous mode with pressure settings 75, 85, and 125 mmHg respectively, and error percentages of -0.60%, 0.93%, and -1.81% for the intermittent mode with pressure settings 75, 85, and 125 mmHg respectively. Similar error percentages were achieved using the wound phantom, namely -0.56% and -0.20% for the continuous and intermittent modes respectively for the pressure setting 85 mmHg. These results show that this low-cost prototype can fulfill the requirements of an NPWT device. In addition, this paper has documented a new method of benchmarking via a Gas Flow Analyzer. A limitation of this study is that it did not conduct clinical trials and that the prototype was not tested with wound phantoms that can accurately simulate the flow of exudate.

For future studies, several possible improvements to the system could be implemented, such as adding an alternate power source to enable portability or adding RTC or an internet connection to enhance timer accuracy and allow remote system control. Additionally, a clinical trial over a longer period should be done to measure

the NPWT prototype's full capabilities in performing a complete negative pressure therapy. It is hoped that the results of this research further increase local content for more affordable NPWT systems, spreading access to better treatment of diabetic ulcers.

Acknowledgments

This research was partly supported by PUTI Pascasarjana 2023 Grant No. NKB-249/UN2.RST/HKP.05.00/2023 from Universitas Indonesia.

REFERENCES

[1] S. Y. Tan *et al.*, "Type 1 and 2 diabetes mellitus: A review on current treatment approach and gene therapy as potential intervention," *Diabetes & Metabolic Syndrome: Clinical Research & Reviews*, vol. 13, no. 1, pp. 364–372, 2019, https://doi.org/10.1016/j.dsx.2018.10.008.

[2] N. G. Forouhi and N. J. Wareham, "Epidemiology of diabetes," *Medicine*, vol. 47, no. 1, pp. 22–27, 2019, https://doi.org/10.1016/j.mpmed.2018.10.004.

[3] D. L. Eizirik, L. Pasquali, and M. Cnop, "Pancreatic β-cells in type 1 and type 2 diabetes mellitus: different pathways to failure," *Nature Reviews Endocrinology*, vol. 16, no. 7, pp. 349–362, 2020, https://doi.org/10.1038/s41574-020-0355-7.

[4] B. O. Roep, S. Thomaidou, R. van Tienhoven, and A. Zaldumbide, "Type 1 diabetes mellitus as a disease of the β-cell (do not blame the immune system?)," *Nature Reviews Endocrinology*, vol. 17, no. 3, pp. 150-161, 2021, https://doi.org/10.1038/s41574-020-00443-4.

[5] S. Padhi, A. K. Nayak, and A. Behera, "Type II diabetes mellitus: a review on recent drug based therapeutics," *Biomedicine & Pharmacotherapy*, vol. 131, p. 110708, 2020, https://doi.org/10.1016/j.biopha.2020.110708.

[6] U. Galicia-Garcia *et al.*, "Pathophysiology of Type 2 Diabetes Mellitus," *Int. J. Mol. Sci.21*, vol. 21, no. 17, p. 6275, 2020, https://doi.org/10.3390/ijms21176275.

[7] K. Ogurtsova *et al.*, "IDF diabetes Atlas: Global estimates of undiagnosed diabetes in adults for 2021," *Diabetes Res Clin Pract*, vol. 183, p. 109118, 2022, https://doi.org/10.1016/j.diabres.2021.109118.

[8] M. Jalilian, P. A. Sarbarzeh, and S. Oubari, "Factors related to severity of diabetic foot ulcer: A systematic review," *Diabetes, Metabolic Syndrome and Obesity*, vol. 13, pp. 1835–1842, 2020, https://doi.org/10.2147/dmso.s256243.

[9] R. A. Primadhi and H. Herman, "Diabetic foot: Which one comes first, the ulcer or the contracture?," *World J Orthop*, vol. 12, no. 2, p. 61, 2021, https://doi.org/10.5312/wjo.v12.I2.61.

[10] S. Patel, S. Srivastava, M. R. Singh, and D. Singh, "Mechanistic insight into diabetic wounds: Pathogenesis, molecular targets and treatment strategies to pace wound healing," *Biomedicine & Pharmacotherapy*, vol. 112, p. 108615, 2019, https://doi.org/10.1016/j.biopha.2019.108615.

[11] S. Mohseni, M. Aalaa, R. Atlasi, M. R. Mohajeri Tehrani, M. Sanjari, and M. R. Amini, "The effectiveness of negative pressure wound therapy as a novel management of diabetic foot ulcers: an overview of systematic reviews," *J Diabetes Metab Disord*, vol. 18, no. 2, pp. 625–641, 2019, https://doi.org/10.1007/s40200-019-00447-6.

[12] F. Bekele, L. Chelkeba, G. Fekadu, and K. Bekele, "Risk factors and outcomes of diabetic foot ulcer among diabetes mellitus patients admitted to Nekemte referral hospital, western Ethiopia: Prospective observational study," *Annals of Medicine and Surgery*, vol. 51, pp. 17–23, 2020, https://doi.org/10.1016/j.amsu.2020.01.005.

[13] B. T. Rodrigues, V. N. Vangaveti, R. Urkude, E. Biros, and U. H. Malabu, "Prevalence and risk factors of lower limb amputations in patients with diabetic foot ulcers: A systematic review and meta-analysis," *Diabetes & Metabolic Syndrome: Clinical Research & Reviews*, vol. 16, no. 2, p. 102397, 2022, https://doi.org/10.1016/j.dsx.2022.102397.

[14] F. Dewi and R. J. Hinchliffe, "Foot complications in patients with diabetes," *Surgery (Oxford)*, vol. 38, no. 2, pp. 108–113, 2020, https://doi.org/10.1016/j.mpsur.2019.12.002.

[15] C. Lin, J. Liu, and H. Sun, "Risk factors for lower extremity amputation in patients with diabetic foot ulcers: A meta-analysis," *PLoS One*, vol. 15, no. 9, p. e0239236, 2020, https://doi.org/10.1371/journal.pone.0239236.

[16] M. Edmonds, C. Manu, and P. Vas, "The current burden of diabetic foot disease," *J Clin Orthop Trauma*, vol. 17, pp. 88–93, 2021, https://doi.org/10.1016/j.jcot.2021.01.017.

[17] D. Dayya, O. J. O'Neill, T. B. Huedo-Medina, N. Habib, J. Moore, and K. Iyer, "Debridement of Diabetic Foot Ulcers," *Adv Wound Care (New Rochelle)*, vol. 11, no. 12, pp. 666–686, 2022, https://doi.org/10.1002/14651858.cd003556.pub2.

[18] S. Flores-Escobar, F. J. Álvaro-Afonso, Y. García-álvarez, M. López-Moral, J. L. Lázaro-Martínez, and E. García-Morales, "Ultrasound-Assisted Wound (UAW) Debridement in the Treatment of Diabetic Foot Ulcer: A Systematic Review and Meta-Analysis," *Journal of Clinical Medicine*, vol. 11, no. 7, p. 1911, 2022, https://doi.org/10.3390/jcm11071911.

[19] W. H. Tettelbach, S. M. Cazzell, B. Hubbs, J. L. D. Jong, R. A. Forsyth, and A. M. Reyzelman, "The influence of adequate debridement and placental-derived allografts on diabetic foot ulcers," *J Wound Care*, vol. 31, pp. S16–S26, 2022, https://doi.org/10.12968/jowc.2022.31.Sup9.S16.

[20] A. J. Pérez-Panero, M. Ruiz-Muñoz, A. I. Cuesta-Vargas, and M. Gónzalez-Sánchez, "Prevention, assessment, diagnosis and management of diabetic foot based on clinical practice guidelines A systematic review," *Medicine*, vol. 98, no. 35, 2019, https://doi.org/10.1097/MD.0000000000016877.

[21] R. G. Sibbald and E. A. Ayello, "Total Contact Cast for Diabetic Foot Ulcers: An Underused 'Gold Standard,'" *Adv Skin Wound Care*, vol. 32, no. 6, p. 247, 2019, https://doi.org/10.1097/01.asw.0000558272.10192.c5.

[22] R. E. Horch *et al.*, "Topical negative-pressure wound therapy: emerging devices and techniques," *Expert review of medical devices*, vol. 17, no. 2, pp. 139–148, 2020, https://doi.org/10.1080/17434440.2020.1714434.
[23] S. Borys, J. Hohendorff, C. Frankfurter, B. Kiec-Wilk, and M. T. Malecki, "Negative pressure wound therapy use in diabetic foot syndrome—from mechanisms of action to clinical practice," *Eur J Clin Invest*, vol. 49, no. 4, p. e13067, 2019, https://doi.org/10.1111/ECI.13067.
[24] J. Przybek-Mita, D. Bazaliński, M. T. Szewczyk, D. Kardyś, B. Mańkowski, and P. Więch, "Nurses' Readiness to Undertake Controlled Negative Pressure Therapy in the Treatment of Chronic Wounds—Research Report," *International Journal of Environmental Research and Public Health*, vol. 20, no. 4, p. 3388, 2023, https://doi.org/10.3390/ijerph20043388.
[25] A. Orlov and A. Gefen, "Effective negative pressure wound therapy for open wounds: The importance of consistent pressure delivery," *Int Wound J*, vol. 20, no. 2, pp. 328–344, 2022, https://doi.org/10.1111/iwj.13879.
[26] M. S. A. Shehata *et al.*, "Effectiveness of Negative Pressure Wound Therapy in Patients with Challenging Wounds: A Systematic Review and Meta-analysis," *Wounds*, vol. 34, no. 12, pp. E126–E134, 2022, https://doi.org/10.25270/WNDS/21061.
[27] Y. Wu, G. Shen, and C. Hao, "Negative pressure wound therapy (NPWT) is superior to conventional moist dressings in wound bed preparation for diabetic foot ulcers: A randomized controlled trial," *Saudi Med J*, vol. 44, no. 10, pp. 1020–1029, 2023, https://doi.org/10.15537/smj.2023.44.20230386.
[28] S. J. Poteet, S. A. Schulz, S. P. Povoski, and A. H. Chao, "Negative pressure wound therapy: device design, indications, and the evidence supporting its use," *Expert Review of Medical Devices,* vol. 18, no. 2, pp. 151–160, 2021, https://doi.org/10.1080/17434440.2021.1882301.
[29] P. Agarwal, R. Kukrele, and D. Sharma, "Vacuum assisted closure (VAC)/negative pressure wound therapy (NPWT) for difficult wounds: A review," *J Clin Orthop Trauma*, vol. 10, no. 5, pp. 845–848, 2019, https://doi.org/10.1016/J.JCOT.2019.06.015.
[30] S. Normandin *et al.*, "Negative Pressure Wound Therapy: Mechanism of Action and Clinical Applications," *Semin Plast Surg*, vol. 35, no. 3, pp. 164–170, 2021, https://doi.org/10.1055/s-0041-1731792/id/jr01315-26/bib.
[31] M. Wynn and S. Freeman, "The efficacy of negative pressure wound therapy for diabetic foot ulcers: A systematised review," *J Tissue Viability*, vol. 28, no. 3, pp. 152–160, 2019, https://doi.org/10.1016/j.jtv.2019.04.001.
[32] K. E. Davis, J. Bills, D. Noble, P. A. Crisologo, and L. A. Lavery, "Ultraviolet-A Light and Negative-Pressure Wound Therapy to Accelerate Wound Healing and Reduce Bacterial Proliferation," *J Am Podiatr Med Assoc*, vol. 113, no. 1, 2023, https://doi.org/10.7547/20-251.
[33] S. Ji *et al.*, "Consensus on the application of negative pressure wound therapy of diabetic foot wounds," *Burns Trauma*, vol. 9, p. 18, 2021, https://doi.org/10.1093/burnst/tkab018.
[34] R. Cuomo, L. Grimaldi, G. Nisi, I. Zerini, F. R. Giardino, and C. Brandi, "Ultraportable Devices for Negative Pressure Wound Therapy: First Comparative Analysis," *Journal of Investigative Surgery*, vol. 34, no. 3, pp. 335–343, 2019, https://doi.org/10.1080/08941939.2019.1616009.
[35] O. Bota *et al.*, "Topical negative pressure wound therapy enhances the local tissue perfusion-A pilot study," *Microvasc Res*, vol. 140, p. 104301, 2022, https://doi.org/10.1016/j.mvr.2021.104301.
[36] A. Gupta ACDEF *et al.*, "Negative pressure wound therapy in surgical practice: an Institutional experience from a tertiary center of North India," *Polish Journal of Surgery*, vol. 95, no. 1, pp. 1–7, 2022, https://doi.org/10.5604/01.3001.0015.8170.
[37] P. Madrigal, T. Moshal, R. Bernabe, H. Yenikomshian, and J. Gillenwater, "A comparison of negative pressure wound therapy modalities, VAC versus non-commercial NPWT alternatives: A systematic review of RCTs/CCTs," *J Tissue Viability*, vol. 31, no. 4, pp. 630–636, 2022, https://doi.org/10.1016/j.jtv.2022.10.002.
[38] W. K. Albayati, S. Al Youha, A. A. Ali, and Z. Fakhra, "A Randomized Controlled Trial to Assess the Cost-effectiveness of a Novel, Simple Modification to the Negative Pressure Wound Therapy System," *Plast Reconstr Surg Glob Open*, vol. 9, no. 8, 2021, https://doi.org/10.1097/gox.0000000000003787.
[39] D. Xing, Z. Yang, Z. Dong, J. Wei, X. Zheng, and W. Li, "A modified negative pressure wound therapy for the treatment of refractory wounds A preliminary study," *Medicine*, vol. 99, no. 28, 2020, https://doi.org/10.1097/md.0000000000021148.
[40] R. Farré *et al.*, "Device for Negative Pressure Wound Therapy in Low-Resource Regions: Open-Source Description and Bench Test Evaluation," *J Clin Med*, vol. 11, no. 18, p. 5417, 2022, https://doi.org/10.3390/jcm11185417/s1.
[41] H. G. B. Cocjin, J. K. P. Jingco, F. D. C. Tumaneng, and J. M. R. Coruña, "Wound-Healing Following Negative-Pressure Wound Therapy with Use of a Locally Developed AquaVac System as Compared with the Vacuum-Assisted Closure (VAC) System," *Journal of Bone and Joint Surgery - American Volume*, vol. 101, no. 22, pp. 1990–1998, 2019, https://doi.org/10.2106/jbjs.19.00125.