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Development and characterization of an automated portable wound irrigation device for diabetic ulcers

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ABSTRACT

Patients with diabetes mellitus may experience peripheral neuropathy and extremity system impairment, which may lead to ulceration if the treatments are delayed. Diabetic ulcers, unfortunately, are chronic, which require proper treatments, including debridement and bacterial removal using an irrigation device. To date, commercial irrigation devices included pulsed-lavage, bulb syringe, and gravity bags. Unfortunately, the devices have limitations in terms of portability, measurability, controllability, and disposability. To tackle the limitations, this study aims to design, fabricate, and characterize an automated portable wound irrigation device (Apdice), which is controllable non-disposable, and portable. The device was designed and fabricated using a lightweight construction, a rechargeable battery, and non-disposable materials to support the portability and non-disposable means. Meanwhile, the proportional-derivative-integral controller with its peripheral components were featured to enable controllability. Furthermore, the device was also tested regarding the contamination using a particle counter, and appeared to be contamination free. In short, Apdice showed a robust technological performance. However, it is also worth the try to test the contamination test against biological agents to guarantee the biocompatibility of the device.

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1. INTRODUCTION

Diabetic ulcers were common in patients with diabetes mellitus (DM) [1]. Arising from peripheral neuropathy along with mechanical changes in the foot architecture, ulcers often lead to limb loss if proper treatments were delayed. Diabetic foot ulcers that are one of the main causes of disability are responsible for more hospitalizations than any other complications due to DM [2], [3]. The incidence of the diabetic foot has increased due to the worldwide prevalence of DM and the prolonged life expectancy of diabetic patients [3]. A previous study showed that a lower limb is amputated every 30 s due to DM, and the average annual cost for a diabetic foot is $8,659 per patient [3]. In a recent meta-analysis, the pooled odd ratio (OR) of the incidence of decubitus ulcers in patients with DM was 1.74 (95% confidence interval (CI) 1.40 to 2.15) compared with patients without DM [4], [5]. At the foot surface, decubitus ulcers could occur at the heel, malleolus, and occiput.

The gold standards for diabetic foot ulcer treatments include debridement, infection management, and off-loading of the ulcer [6]. The mentioned treatment can carried out using wound irrigation, a technique to perfuse a steady flow of solution across an open wound surface to achieve wound hydration, remove deeper debris and necrotic tissues, and assist with the visual examination [7], [8]. Furthermore, the irrigation can help preventing premature surface healing over an abscess pocket or infected tract [7].

The wound irrigation strategy was focused on two main aspects: the irrigation technique (pressure-related) and the irrigated solution. Current techniques that are commonly used are pulse lavage system, pressurized canisters, and squeezable bags with an attached tip end [9]. Various sizes of bulb syringes and needles have also been used [9]. The irrigated solutions also varied, including saline water, tap water, castile soap, and chloride [9], [10].

Irrigation techniques have been compared and evaluated by numerous studies to obtain the most effective method used in wound treatments. Mundy *et al.* [11] compared a pulse lavage system with a gravity bag containing normal saline to observe the irrigation time. The results showed that the gravity irrigation resulted in the fastest and most effective procedure. This study also mentioned that the gross expense of pulse lavages, which costed approximately 3.3 times more than of gravity lavages. However, the gravity bag method should be placed at least above 6 ft to gain a proper speed for wound irrigation. Furthermore, Owens *et al.* [10] compared the efficacy of the bacterial removal between a commercially pulsed-lavage at a pressure range of 6 psi to 70 psi and a bulb syringe. The results indicated that both treatments were effective in removing 75% of the bacteria. Unfortunately, after forty-eight hours the bacterial level in the pulsed lavage group rebounded to 94% of the original level. However, pulse lavages produced a higher amount of pressure compared with a standard bulb syringe and a syringe-plunger system [12]. This amount of pressure was still effective to decrease the presence of bacteria in lower extremity wounds [12].

The use of pulsed lavages can be challenging since wound irrigations require various amounts of pressure according to clinical cases [13]. In addition, pulse lavages are relatively high-cost, disposable, and not portable. On the other hand, the use of gravity bags and bulb syringes are not applicable for pressure control, which may compensate effective wound irrigations [14], [15]. Moreover, these systems may lead to hand strain of the operator because the fluid must be released manually by squeezing the bag or pushing the bulb syringe repeatedly to complete irrigate the wound [16]. Clearly, more precise evidences are required regarding the clinical effects of pulse lavages, gravity bags, and bulb syringes.

This study aims to design, fabricate, and characterize an automated portable wound irrigation device (Apdice) with controllable, non-disposable, and portable characteristics. The device was designed and fabricated using a lightweight construction made of 3D-printed polylactic acid (PLA). The device was also equipped with a rechargeable battery, and non-disposable materials to support the portability and non-disposable means.

2. RESEARCH METHOD

2.1. Mechanical construction and components

The mechanical construction of Apdice comprised two main compartments: casing Figure 1(a) and handgrip Figure 1(b). The two compartments were made of PLA and fabricated using fused deposition modeling (FDM; 3D printing) [17]. PLA is considered as a lightweight material [18] and is commonly used in prototyping [19]. The size of the casing compartment was designed according to the size of components mounted inside the compartment, while the handgrip was designed with a stronger consideration on the ergonomic viewpoint. The casing compartment housed four electrical components Figure 1(c): an Arduino Nano microcontroller, a Taffware DP-521 12 V DC pump, an L298N motor driver, and a 3000 mAh Baseus battery. Meanwhile, the handgrip compartment consisted of a YF-S401 flow sensor, an SSD1306 OLED monitor, a switch button, a potentiometer, and a nozzle tip. The electrical components inside the handgrip compartment were connected to the electrical components in the casing compartment using a multifunctional jumper cable.

2.2. Electrical circuitry

The components of Apdice were divided into five units: a power supply, a control unit, an actuator, a sensor, and a peripheral unit, working systematically as shown in Figure 2. The battery acted as a power supply with two output types. The first one was featured with a 12 V output and the other one was featured with a 5 V output.

The control unit regulated the negative feedback system of the device, which consisted of an Arduino Nano microcontroller, a motor driver, a potentiometer, and a light emitting diode (LED) display. Arduino provided an open-source control board platform that has been widely used in medical device prototyping [17], [20], [21]. In this study, Arduino received an instruction from the potentiometer and continued the instruction by sending a pulse-width modulation (PWM) signal to the motor driver. The LED display was used to show the setpoint and the real-time pressure. Subsequently, a pump worked to actuate a positive pressure with-based on the datasheet-a range of 0 to 70 psi. The motor driver converted a digital PWM signal from Arduino to an analog signal to the pump in the form of voltage. As a result, the irrigated solution could be perfused from the reservoir to the wound bed. To facilitate the control system regulation, the correlation between the output pressure level and the transferred PWM signal was characterized. Finally, a flow sensor was used to acquire the actual pressure level produced by the pump.

(a) (b) (c)

Figure 1. The casing compartment design of an (a) Apdice device, (b) interior design of casing compartment for electrical components, and (c) the handgrip compartment design

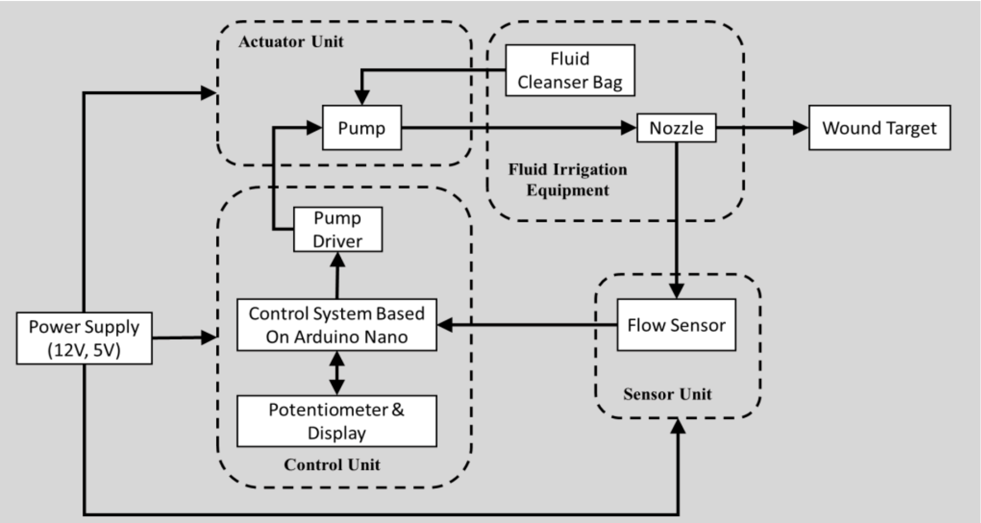


Figure 2. The component structure of the device

2.3. Control system configuration

The automatic control system was implemented in the device by a close loop system, shown in Figure 3. To begin with, the microcontroller received a value measured by the sensor. The value discrepancy between the measured value and the setpoint was considered as an error signal, which was subsequently converted to the digital signal using a 10-bit analog-digital converter (ADC) of the Arduino. The error signal stimulated the Arduino to regulate the 8-bit PWM signal output. The PWM signal, subsequently, was converted by a pump driver into an analog signal. In addition, a flow sensor was integrated to receive feedback. The feedback was used to acquire the set pressure value a delivered to the wound bed. The sensor produced the feedback signal so that the pressure could be controlled at the setpoint. There were two controllers used in this study: on-off and the proportional-integral-derivative (PID).

The on-off controller was designed by adding and subtracting gradually regarding the PWM point. When the setpoint was not yet reached, the PWM point would increase accordingly. In the contrary, when the pressure value exceeded the setpoint, the PWM point would decrease gradually. The addition and subtraction of the PWM were set every 200 ms with which the updated time of the real data from the sensor was 1 s. Theoretically, the control system either added or subtracted 5 points of the PWM after one second.

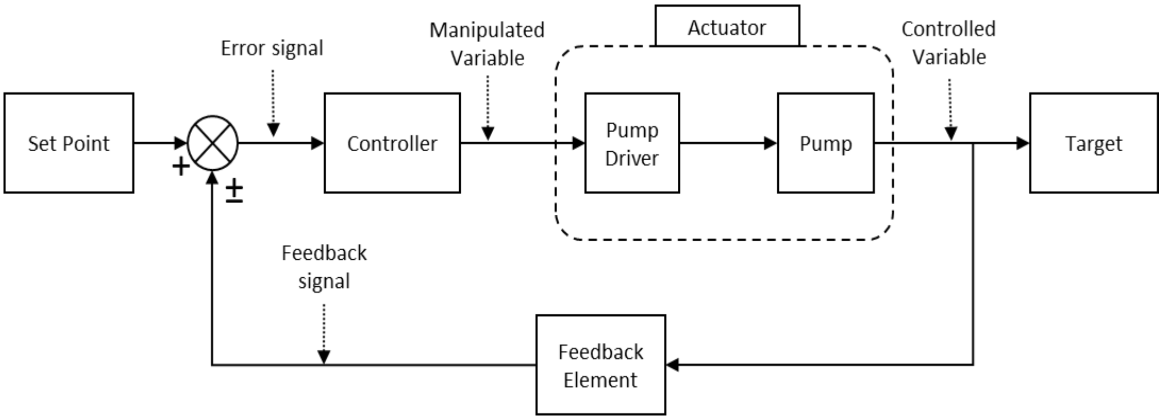


Figure 3. Block diagram of the Apdice closed-loop system

Meanwhile, the PID controller was configured heuristically (by trial and error), thereby resulting into four configurations: P controller, PD controller, PI controller, and PID controller Table 1 [20], [22]. Furthermore, the transient response of each configuration was analyzed using seven parameters to determine the performance of each controller. The parameters included rise time, settling time, overshoot, mean pressure value, root mean square error (RMSE), and maximum spike [23], [24]. In terms of the feedback system, the pressure values were obtained by the sensor for each controller every second.

Table 1. Controller's constant (s) configurations

Configuration	K_p	K_i	K_d
P	1.5	-	-
PD	1.5	-	0.5
PI	1.5	1	-
PID	1.5	1	0.5

2.4. Testing mechanisms

2.4.1. Sensor calibration

The sensor was calibrated to confirm the performance of the sensor according to the datasheet. In this study, two types of sensors were used: a pressure transducer and a YF-S401 water flow sensor. The pressure transducer was calibrated by PT. Sucofindo. The calibration result of the sensor was used as a baseline for the following measurements. On the other hand, a YF-S401 water flow sensor was calibrated inhouse by calculating the number of pulses that were received by Arduino when the sensor was drained with a 1,000 ml volume of water. Afterwards, the ratio between volume and pulse was obtained. To gain the flow rate, Arduino acquired the number of pulses per second from the sensor and multiplied it with the ratio. Thus, the flow rate was generated in mL/s.

2.4.2. Pump characterization

The Apdice device used a Taffware DP-521 pump that had a maximum pressure of 70 psi, according to the datasheet. The pump was characterized using a water flow sensor prior to the installation by acquiring the dataset of pressure values for every increment of the PWM point from 1 to 255. The flow rate was recorded for 30 seconds for each PWM point with an interval of 30 s to provide a time window for the pump to the initial state (P=0 psi). The flow rate was converted into pressure using the Bernoulli equation. The data acquisition was repeated three times.

2.4.3. Pressure measurement

In the clinical setting, wound irrigation devices are performed with various angles regarding the wound location. In this study, three different angles were used: 0° (horizontal), 45°, and 90° (vertical) Figure 4. For each testing angle, the handgrip of the device was mounted on a fixed position and confirmed using a water pass and a protractor. As a result, the flow rate at the nozzle tip were measured. The measured flow rate was converted to pressure using the Poiseuille equation. To confirm the measurement results, the pressure at the pump end was measured using a pressure transducer.

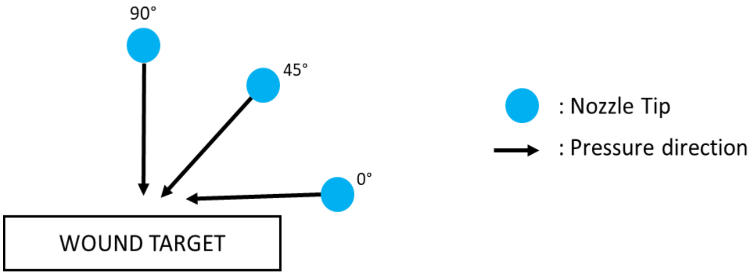


Figure 4. The illustration of pressure measurement

2.4.4. Particle contamination test

Since the irrigated solution was perfused through various components made of different materials (e.g., water pump and hose), it was necessary to ensure that the irrigated solution was not contaminated due to the contact with the components. The particle contamination test used a 500 ml volume of tap water that was irrigated through the device with a vertical setting. The particle count and pH level of the water before and after the irrigation were measured using a total dissolved solid (TDS) meter and a pH meter with 30 repetitions. Subsequently, the measurement results were compared using t-tests.

3. RESULTS

3.1. Mechanical construction

The 3D printed casing compartment combined with the required electrical components resulted in a similar dimension to the design, with a length of 175 mm, a width of 120 mm, and a height of 160 mm. The total mass of the casing compartment was approximately 1,500 g. Meanwhile, the handgrip compartment had a dimension of approximately 80 mm, 40 mm, and 60 mm for the length, width, and height, consecutively. The mass of the handgrip was 70 g. Therefore, the total mass of the Apdice device was approximately 1,570 g.

3.2. Pressure measurement

The pressure measurement was performed at the three different angles for each controller configuration with a duration of 30 minutes for every angle and configuration. The behavior of the controller to achieve the setpoint was observed using transient response parameters that were divided into two categories: rise performance and oscillation characteristics. The rise performance was analyzed using three parameters: rise time, settling time, and overshoot as shown in Table 2. Meanwhile, the oscillation characteristics were illustrated by four parameters: mean, standard deviation, RMSE, and maximum spike as shown in Table 3. Unfortunately, the P and PD controllers failed to produce required responses during the measurement, thereby labeled not available (N/A). The main reason was presumably due to the inability of the two controllers to produce a sufficient PWM signal of 50 to actuate the pump.

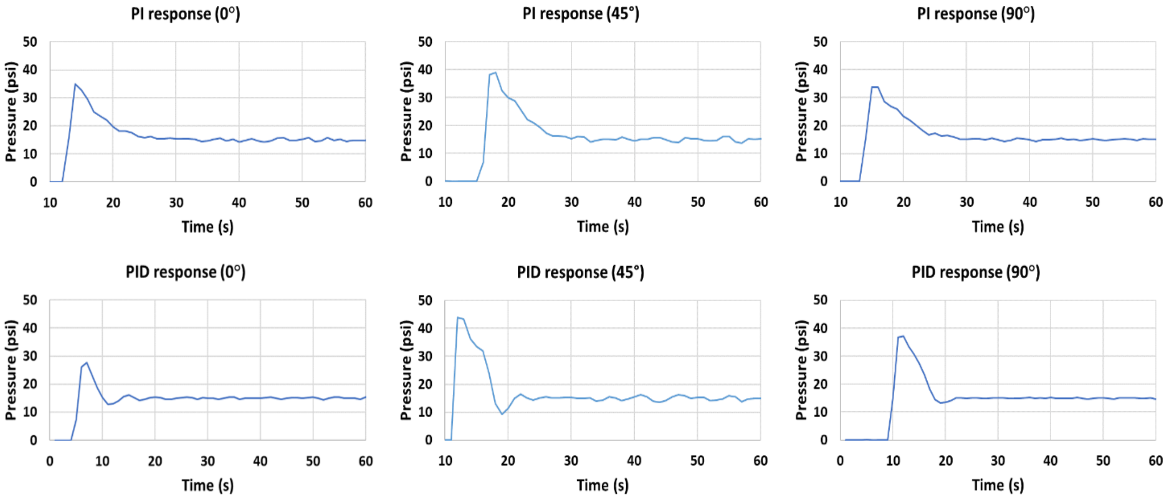
Table 2. Rise performance of each controller based on angel positions

Angel	Configuration	Rise Time (s)	Settling Time (s)	Overshoot (%)
Horizontal (0°)	P	N/A	N/A	N/A
	PD	N/A	N/A	N/A
	PI	13.00	25.00	57.11
	PID	6.00	14.00	45.75
45°	P	N/A	N/A	N/A
	PD	N/A	N/A	N/A
	PI	16.00	29.00	58.97
	PID	11.00	20.00	65.87
Vertical (90°)	P	N/A	N/A	N/A
	PD	N/A	N/A	N/A
	PI	14.00	28.00	55.62
	PID	10.00	22.00	59.82

The rise performance of the PI and PID controller varied as shown in Figure 5. The rise time values of the PID controller were lower than of the PI controller for each angle. Similarly, the required time for the PID controller to settle at the setpoint for each angle was shorter than the PI controller. These results mean that the rise performance of the PID controller for each angle was more powerful than the PI controller. Consequently, the PID controller had a higher overshoot value than the PI controller at the angle of 45° and 90°. This behavior commonly emerged when the controller was more aggressive to reduce the rise time [25]. The rise performances of the two controllers were elaborated in Table 2.

Table 3. Oscillation characteristics of each controller based on angel position

Angel	Configuration	Mean (psi)	St. Dev. (± psi)	RMSE (± psi)	Max Spike (%)
Horizontal (0°)	P	N/A	N/A	N/A	N/A
	PD	N/A	N/A	N/A	N/A
	PI	15.00	1.46	0.62	16.48
	PID	15.00	0.81	0.45	5.24
45°	P	N/A	N/A	N/A	N/A
	PD	N/A	N/A	N/A	N/A
	PI	15.00	1.77	0.70	16.48
	PID	15.00	1.83	0.79	13.04
Vertical (90°)	P	N/A	N/A	N/A	N/A
	PD	N/A	N/A	N/A	N/A
	PI	15.00	1.47	0.52	9.31
	PID	15.00	1.43	0.44	10.61



PI response (0°)

PI response (45°)

PI response (90°)

PID response (0°)

PID response (45°)

PID response (90°)

Figure 5. Result plots of the rise performance of each controller

In terms of oscillation characteristics, the PID controller generally presented a better performance compared with the PI controller as shown in Figure 6. However, the RSME of the PID controller at 45° was higher (± 0.79 psi) than of the PI controller (± 0.70 psi). Moreover, the precision of the controller to deliver a stable continuous pressure was observed by showing the standard deviation of each controller. The PI controller was more precise than the PID controller at one angle only (45°), indicated by a lower standard deviation of the PI controller (1.77) than of the PID controller (1.83). Furthermore, the maximum spike of the PID controller was also higher (10.61%) than of the PI controller (9.31%) when the device was used vertically. The oscillation characteristics of the two controllers were elaborated in Table 3.

3.3. Particle contamination test

The particle contamination tests were conducted 30 times by distinguishing the setups of the irrigated solution before and after the irrigation. The particle counting using a total dissolved solid (TDS) level and pH level were used as parameters to analyze the fluid contamination. Accordingly, the t-test for TDS results showed a statistically significant similarity of the particle count between before and after the irrigation Table 4. Moreover, the results also indicated that this device was free from particle contamination, complying the requirement of a wound irrigation device [26]. On the contrary, the t-test for the pH results implied a statistically significant difference of pH between before and after the irrigation. However, the average pH level between before (6.89 ± 0.07) and after (6.96 ± 0.06) the irrigation was only 0.07 apart. The pH level after the irrigation was also still in the safe range.

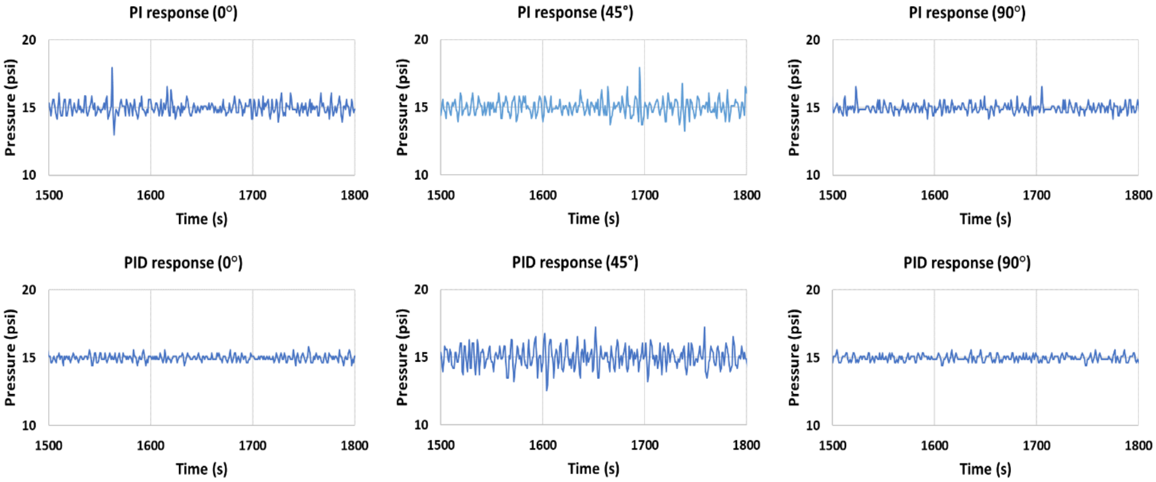


Figure 6. Result plots of the oscillation characteristics of each controller

Table 4. T-test of TDS and pH parameter

Parameter	Before	After	p-value
TDS (ppm)	165.67±1.80	165±3	0.326
pH	6.89 ± 0.07	6.96 ± 0.06	4.5E-09

4. DISCUSSION

One of the desirable requirements of wound irrigation devices is the ability to provide a controllable and stable pressure [27]. As mentioned, this study utilized the PID control system to maintain the output pressure of the device, thereby configuring four types of controllers: P, PI, PD, and PID controllers. It was proven that P and PD controllers were not applicable since the PWM values of the two controllers were inadequate to trigger the pump to work. P controller are commonly used in various control system applications which offsets are tolerated, while the D controller is set to anticipate the future behavior of the error signal by considering its rate of change [23]. Nonetheless, the pump used in this study had the PWM range to operate properly, which was known as a saturation condition of the physical limit. The P and PD controller could not overcome this physical limitation and only produced the steady-state error [25]. Therefore, the addition of I controller in the system was imperative. It was due to the function of the I controller in calculating the steady-state error continuously and delivering the higher PWM signal to regulate the pump.

Regarding this circumstance, the only available configurations were the PI and PID controllers. Hence, the two controllers were compared to determine the compatibility with the device requirements. According to the results, the PID controller showed superiority against the PI controller in terms of response characteristics. Furthermore, the PID controller could achieve pressure stability faster than the PI controller. In addition, the PID controller also resulted in a lower error than the PI controller. The output pressure consistency of the PID controller was also notable at a pressure of 15 psi, which was the recommended pressure for wound healing and debridement [27], [28].

This study also considered the angle dynamics, noticing that wound irrigation procedures can be performed at various angles according to the wound location [29], thereby three different angles: 0° (horizontal), 90° (vertical), and 45°. Presumably, different angles of operation would result in different output pressure values. Nonetheless, the use of PID control system preserved the output pressure at the same level as the setpoint, regardless the angles. This result also indicated that the use of the PID controller allowed the device to be used in multi-angle situations, enabling multi-location wound irrigation procedures.

5. CONCLUSION

An automated portable wound irrigation device (Apdice) device has been successfully fabricated and characterized. The use of a rechargeable battery and a lightweight construction of the device allowed for portability purposes. Meanwhile, the use of the PID controller came up with an ease of controllability. The PID controller showed the most robust pressure rise performance and oscillation characteristics among other controllers. The contamination tests using a TDS meter and a pH meter presented no particle contamination of the irrigated solution. However, microbial tests are still required to assure that the device is free from microbial contaminants. Moreover, clinical trials are still required to clinically confirm the efficacy of the device on the suited patients.

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