International Journal of
INTELLIGENT SYSTEMS AND APPLICATIONS IN ENGINEERING
ISSN:2147-6799 www.ijisae.org Original Research Paper

Design, Fabrication and Technical Assessment of Isolated Multi Patient VAC systems for Diabetic Wound Ulcers

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Submitted: 31/12/2023 **Revised**: 07/02/2024 **Accepted**: 15/02/2024

Abstract: In India ranks first for the highest diabetic population, surpassing 100 million individuals, and is known as the "Diabetic Capital of the World." Almost 15–25% of diabetic patients are suffering from diabetic foot ulcers, considered non- healing acute and chronic wounds that lead to amputation. The treatment is also prolonged and highly expensive, which is not affordable for poor people. The new Vacuum-Assisted Closure (VAC) device is an advanced method of conventional closure designed to treat multiple patients. It can also be extended to four patients, where a minimum of 2–4 patients can be treated. The primary advancement is the isolation of internal and external circuits. This setup provides infection-free treatment for patients. This single device can provide parameters for treating different types of wounds with different therapeutic requirements. This device comprises eight heavy-duty pumps that help in treating in different modes and can still be used as a portable device. Since it is provided with multiple inlet and outlet ports, it can be used in public hospitals where it is difficult to provide treatment for more than 100 patients per day with diabetic foot ulcers. This single device can minimise the number of VAC devices used and maximise the number of patients treated. Almost 200 patients with diabetic foot ulcers were engaged in and treated with this VAC therapy. The study demonstrates that the Multi-Patient VAC Therapy System helps in faster granulation tissue closure and a better graft rate. A technical assessment has also been performed for each prototype model.

Keywords: *Diabetic Foot Ulcer, Granule Foam, Granulation Tissue Closure, Vacuum Assisted Closure.*

1. Introduction

The suction effect implies the use of both liquid and air, in general pressure application classified into two types: a. positive pressure; and b. negative pressure. The positive pressure corresponds to a compressed flow of air and the negative pressure corresponds to suction (vacuum). Diabetic foot ulcers affect a significant amount of the diabetic population, leading to infection and in the end, amputation. Vacuum treatment is a therapeutic technique that enhances wound healing and aids in the avoidance of amputation. A granular foam dressing and a vacuum device are used in this therapy. It is one of the oldest wound-healing procedures, tracing back to 400 BC when the Greeks used cupping with heated copper bowls [1]. When compared with standard wound care, treating diabetic wounds with VAC Therapy can result in faster wound bed preparation, faster closure, and a higher graft rate. [2] In either intermittent or continuous mode, a vacuum is supplied to the granule foam-dressed area with a silicone rubber cup. The various effects of Negative Pressure in Human Body are shown in Fig 1.

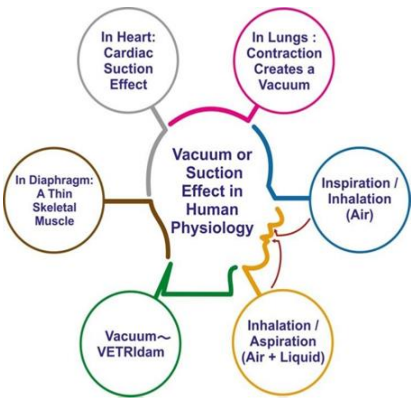

Fig.1. Effects of Negative Pressure in Human Body

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Negative pressure aids in the removal of pus from the wound region, lowering the risk of bacterial infection and edema. The mechanical properties of the granule foam initiate the growth of blood vessels and capillary blood flow. Negative pressure therapy provide numerous benefits including faster granulation and tissue formation, epithelialization, fewer dressing changes, decreased risk of infection. Low treatment costs, exudates control during therapy, concurrent rehabilitation and improved patient tolerance [3]. According to relevant medical statistics NPWT can reduce acute wound healing time by 61% chronic wound healing time by 2–3 times, and save hospitalization costs by 23% [4]. The most common etiologies for DFU are diabetic neuropathy and peripheral arterial disease. The strict ischemic foot is only about 10% of all DFU, with neuropathy involved in 90% of cases. However, in the last few years, the incidence of neuroischemic ulcers has increased, with the most common type being the diabetic foot ulcer [6] This evaluation encompassed the three criteria of product usability in a specific context of use.

1) Effectiveness; 2) Efficiency; and 3) Satisfaction. This device was initially designed to satisfy all requirements for medical equipment, including an ergonomic design for increased comfort and safety as well as increased utilization. When a device is designed with an ergonomic approach, it can be seamlessly integrated into the clinical setting for optimal effectiveness and efficiency in treatment [8].

The use of vacuum therapy in the medical field is illustrated in Figure 2 below

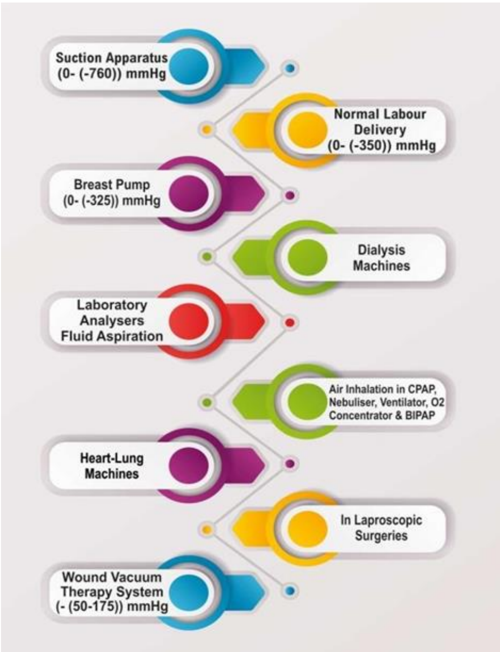

Fig.2. Application of Vacuum in Medical Field

Here, the traditional approach of using a Vacuum Assisted Closure (VAC) device to treat a single patient is advanced by the VAC device developed to deal with multiple patients. This portable device has different modes of operation for treating various patients with different treatment needs. The primary advancement in this technique is the isolation of internal and external circuits that aid in infection-free treatment. Here, we report our first-hand experience with utilising VAC therapy to treat chronic and severe deep wounds and patient evaluations that strengthen its application in clinical settings.

2. Development of Prototypes

When this research started, the Standalone machine cost Rs. 12 lakhs, and the dressing cost per day was Rs. 20,000. Generally, a severe wound patient needs at least 5-12 days of treatment with commonly available devices. This end product is the result of 14 trials of models developed as prototypes. The main aspect of developing 14 trials of VAC machines was to overcome the complications of overheating and electrical issues in the continuous functioning of the device and to ensure a safest treatment with satisfactory results. All these 14 models have been designed and developed as prototypes for the end products by researching clinical studies and dealing with surgeons and patients to customize their needs to provide a wholesome treatment while considering the challenges of giving effective treatment to multiple patients. Serious measures and trials were taken to develop a VAC therapy device that is useful in providing treatment for absolute results with specialized features at an affordable cost. The flow chart delineated in Figure 3 illustrates the procedural intricacies involved in the development of the novel VAC device.

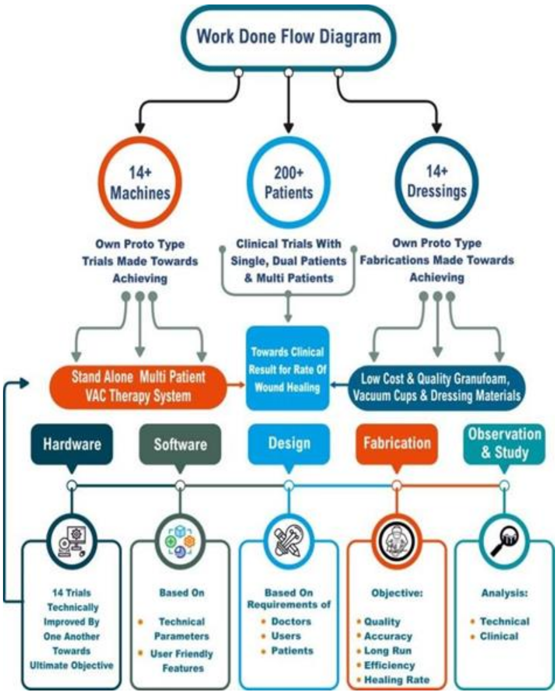

Fig.3. Flow Chart of the Working Process

Each model is distinguished by a unique feature meticulously developed through well-defined practical experiments. The developmental process adhered to a systematic approach, commencing with readily available materials and a logical methodology for the refinement of each model. Notably, these models are characterized by their originality, as they were not replicated from existing vacuum therapy devices in the market, and neither were they influenced by other studies or pre-existing ideas. The emphasis on innovation and independence in design sets these models apart in the realm of vacuum therapy devices The commitment to innovation and a steadfast dedication to uniqueness underscore the unparalleled nature of these models, marking them as pioneering contributions to the field of vacuum therapy devices.

The figure 4 shows all the 14 trials of developed models with advancements in each model

Fig. 4. Developed Prototypes (14+ models)

Fig.5. Isolated Dual Patient VAC System

The final model developed as an Isolated Dual patient VAC system is shown in figure 5

The process of developing this device includes various steps of improvement to make this device sustainable for treatment. The novel inputs into the development of this device is the resultant of deep practical study and analysis on treatment using this device. The advancements and development process are discussed in table 1

Table 1 Development and Advancements of Prototypes

S.No	MODEL	FEATURES	BENEFITS	DRAWBACKS
1	Tiny proto type	Initial stage of VAC	Ultra small with battery	Unable to use for long run
2	Nano suction	Single pump	Can use in Intermittent mode for an hour	Unable to use in continuous mode
3	Nano with timer	Single pump with timer	Enabled analog Timer	Runs only for 6hrs/day in Continuous mode
4	Dual Heavy pump with pressure gauge	Dual pump with timer and pressure monitoring	Enabled with Digital Timer	Can be used in intermittent mode only for 8hrs/day
5	Dual Heavy pump with temp controller	Dual pump with timer, temp. cutoff and analog pressure	Protects from overheating in long-run	Runs only for 10 hrs/day in Continuous mode

6	Tetra Heavy pump with temperature controller	Tetra heavy pumps with temp.cut-off and analog pressure	Can use in Continuous mode for 24hrs	Large in size. weighs 18 kgs
7	Tetra Heavy pump	Tetra pump with timer, temp.cutoff and digital pressure	Can use in Intermittent and Continuous mode for 48hrs/day	Large in size weighs 14 kgs
8	Digital VAC	Tetra tiny pumps with analog Pressure	Can run in Continuous mode for 24 hrs	Same features as model 6. but small in size
9	Dual Tiny pump with temp controller	Same as model 5	But small in size	Runs only for 10 hrs/day in Continuous mode
10	PLC VAC	Tetra pump	Tiny pumps	Runs only for 14 hrs/day in Continuous mode
11	Touch screen based Tetra heavy pump VAC	Digital Pressure monitoring and Temperature	Can run in Continuous mode 48 hrs	Reduced cabinet size but weighs 12 kgs due to heavy pumps
12	Pocket VAC with single pump	Tiny pumps with digital pressure monitoring	Li-ion battery is used	Can be used only for small wounds and runs only 8 hrs/day
13	Pocket VAC with dual pump	Tiny pump with digital pressure control	Operated with battery	Unable to use for more than 16 hrs/day, only Intermittent mode

14	Touch screen based TetraVAC	Tetra tiny pumps with digital pressure control	Less in weight, capable of running 72 hrs	High production cost
15	Touch screen based tiny pump Octa VAC	Twin tetra pumps with digital pressure & Isolated Dual patient	Capable of 100+ hours running until proper granulation forms	Capable of 4+ patients in a single machine to be enhanced

3. Hardware Design

3.1 Pump Module

The pump is a crucial component of this VAC device as it provides negative pressure for therapy. The pump's efficiency plays a significant role in the effectiveness of the treatment. This device employs a novel approach by setting the pumps to withstand overheating during the process.

3.1.1 Octal Pump Setup

Typically, employing a single pump during continuous operation to provide pressure often results in overheating. To prevent overheating, a solution involves the use of four pumps, each capable of operating simultaneously at specific intervals. For the administration of Vacuum Assisted Closure (VAC) therapy to two patients concurrently, eight pumps operating under negative pressure are utilized, organized into two sets with four pumps in each group. These pumps are designed to work alternatively to process the functionality of the device without halt.

3.1.2 Design and Structure of Pumps

These pumps, weighing merely 20 grams of 12V power, generate negative pressures ranging from -50 mmHg to

-200 mmHg to extract exudates from the wound area. The pump's motor is constructed from metal and is encased in plastic, with its operation regulated by atimer.

3.1.3 Different Modes

This device can be used in different modes for different therapeutic requirements at the same time for each patient with different types of wounds. This machine can be used in six combinations of modes, including Intermittent 1 (2 minutes ON and 5 minutes OFF), Intermittent 2 (5 minutes ON and 2 minutes OFF), and Continuous mode (4pumps/each pump 5 minutes ON consequently) for each patient, with a different set combining these three modes.

3.1.4 Dual Functionality

These pumps serve a dual purpose, functioning both as an air pump and a vacuum pump. The vacuum functionality is employed for therapeutic treatment, while the expelled air is utilized to cool the internal cabinet, acting as an air cooler.

3.1.5 Sterile Setup

The pumps are set up with internal tubing that creates an isolated environment, ensuring infection-free treatment. The suitable mode of operation, as recommended by the medical professional, depends on the specific wound condition and the expected healing duration.

3.2 Sensors

There are two sensors used in this VAC device for the safety. Pressure sensor and Temperature sensor are used for their purposes to enable the device function properly and for its durability.

3.2.1 Thermal Sensor

A thermal detector is integrated into the device to monitor pump overheating with programmed cut-off level. The device turns off automatically when temperature level exceeds the temperature cut-off frequency for safety purpose.

3.2.2 Pressure Sensor

A precise MEMS pressure sensor with a 5V rating is used for its accuracy. There are two sensors, one for each patient unit, which monitor pressure changes. This allows for simultaneous monitoring of pressure changes for two patients. The system also has an alarm to alert when there is a pressure change in the applied pressure.

3.3 Suction Tube

The suction tubes are made of silicone come in three different sizes (small, medium, and large) to fit wounds of varying sizes. It connects a canister on one end and a silicone plastic cup on the other. The cup is placed on the wound area, which has a small orifice in granule foam. The suction tube absorbs effluent fluid from the wound and collects it in the canister.

3.4 Canister

A canister is used to collect the exudates from the wound, where the canister is connected to a suction tube on one end and a pump on another end. The canister is also supplied with negative pressure to suck out the exudates. Two canisters are utilized to administer treatment to two patients concurrently, ensuring a sterile treatment environment and facilitating the organized storage of the daily collected exudates volume. In commercially available VAC products, costly disposable canisters are used. In this device commonly available 600ml reusable canisters are used for Economic purposes.

3.5 Dressing Materials

3.5.1 Fabrication of Ultra Low Cost Dressings

The dressing materials used are fabricated in-house with 500-600 micrometer granule foam. It is an Ultra Low Cost dressing with integrity of seal for complete coverage without any minute leakage of pressureapplied. It has the same effect as the expensive dressing foam used. The mechanical properties of granule foam help in rapid healing by establishing blood circulation at the site of the wound, which leads to faster granulation tissue formation and a faster skin graft rate.

3.6 Programmable Logic Controller

A Programmable Logic Controller (PLC) is a device that regulates and oversees all the components within an apparatus. It works like a switch, controlling the front-end and back-end software to ensure the device operates according to the user's input. One notable feature of the PLC is that it directly provides voltage readings in Volts than Millvolts. It avoids the need for signal conditioning circuits.

3.7 Display Screen

This 7-inch touch screen is seamlessly integrated with a Human Machine Interface (HMI). Designed for user convenience, the touch-screen display facilitates easy access to settings and proficiently showcases all necessary parameters. The figure 6 below show the block diagram of the design and function of this VAC system.

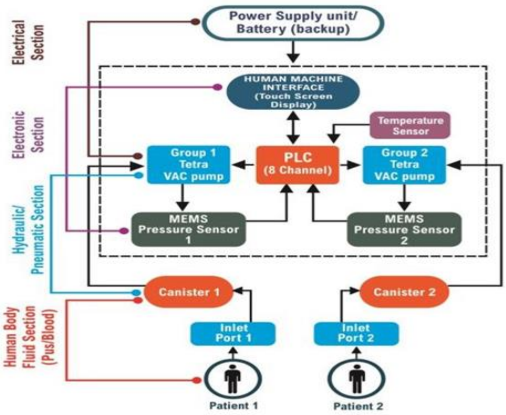

Fig.6. Block Diagram of the System

4. Software Design

The device comes with a unique user interface that provides specialized, patient-specific software with separated front-end controls. The customization of treatment controls is made easy with various control options given for each patient.

Fig.7. Software Design (front-end display screen)

The software makes it more user-friendly and usable in delivering therapy with our VAC device. The front-end system of the software design mainly has controls for Patient mode, Treatment mode, Parameter settings, Main key parameters, and Device history.

The flow chart of the front-end control process is shown in the figure 8 below

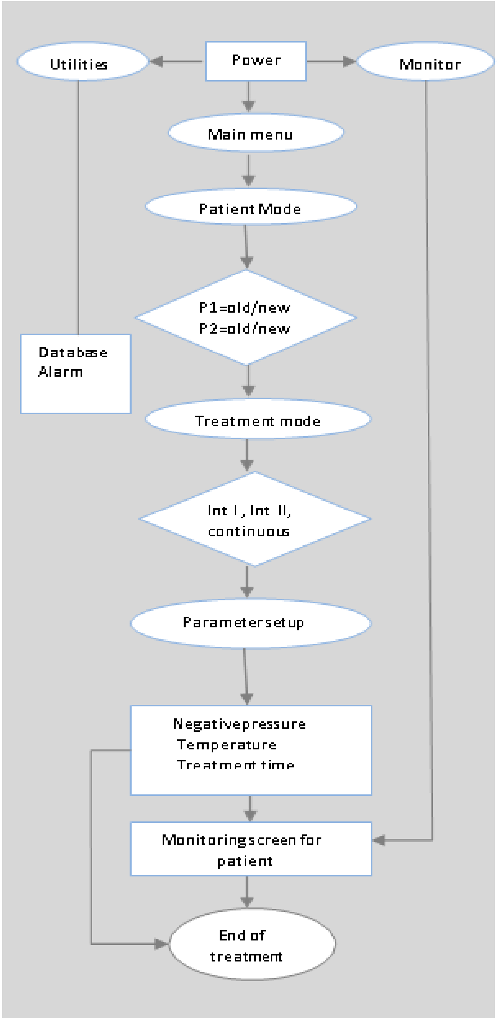

Fig.8. Flow Chart of the Front-end Control Process

4.1 Patient Modes

This feature allows the user to choose the patient mode for delivering treatment to different types of patients. The option provides four different control options for single and dual patients, as well as for old and new patients. With this feature, the user can conveniently set the treatment for patients without any interruptions, and without having to re-set the specified parameters when treating multiple patients with the same device. (Shown in figure 7(b))

4.1.1 Single Patient Mode

This Dual patient VAC therapy device can also be used for a single patient by using this control. This option sets the device in delivering therapy only for a single patient.

4.1.2 Dual Patient Mode

By using this Dual Patient Mode option the user can run this device for two patients at a time.

4.1.3 Old Patient Mode

This control feature has been specifically designed to reset the parameters for patients who have previously undergone treatment with the device. By utilizing this feature, healthcare professionals can avoid the inconvenience of manually configuring the parameters from scratch for each subsequent treatment session. This ensures that patients receive consistent and accurate treatment, while also enhancing the efficiency of the treatment process.

4.1.4 New Patient Mode

This particular control is designed to set the device to operate for a new patient, by configuring all of the parameters required for their treatment from a cleanslate, without any prior information.

4.2 Treatment Modes

The negative pressure can be set from -50 mmHg to 175 mmHg, according to the type of wound. It has three modes Continous, Itermittent 1, and Intermittent 2. These three modes can be used in six combinations of any two modes combined for dual patient treatment.The combinations of modes are,

1. P1- Continuous, P2-Intermittent I
2. P1- Continuous, P2-Intermittent II
3. P1- Continuous, P2- Continuous I
4. P1- Intermittent I, P2- Intermittent II
5. P1- Intermittent I, P2- Intermittent I
6. P1- Intermittent II, P2- Intermittent II

The screen displaying the three treatment modes is shown in the figure 7 (d).

Diagrams representing the Time cycle of the pumps at different modes are shown in the figures (9a, 9b, 9c). Continuous mode – continuous functioning of pumps with alternate cycle, Intermittent 1 - 2 minutes ON and 5 minutes OFF, and Intermittent 2 – 5 minutes ON and 2 minutes OFF.

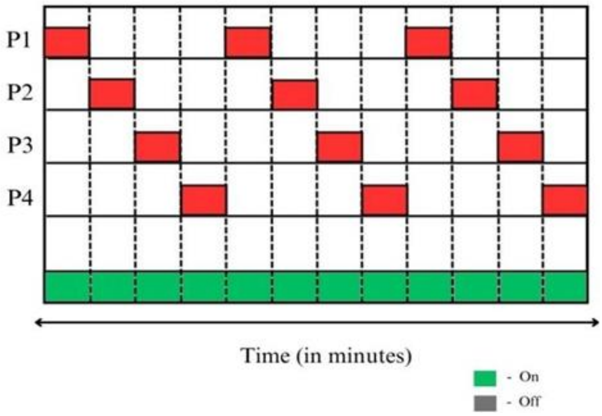

Fig.9(a). Continuous Mode (continuous function)

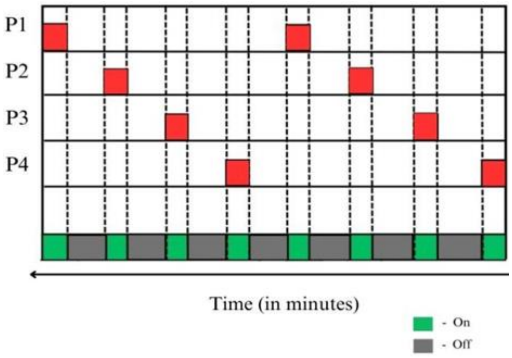

Fig. 9(b). Intermittent 1(2 mins ON - 5 mins OFF)

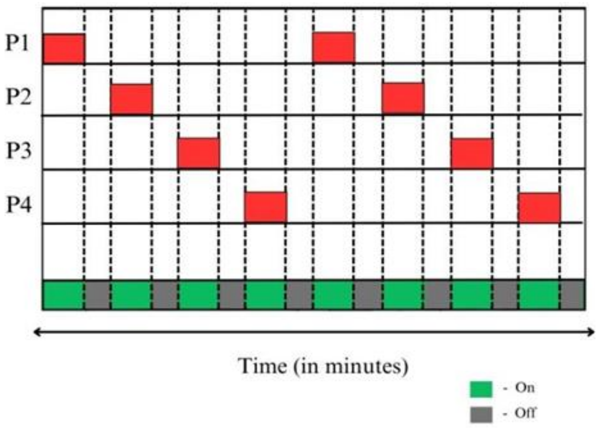

Fig.9(c). Intermittent 2 (5 mins ON – 2 mins OFF)

4.3 Parameter Settings

4.3.1 Pressure

The pressure settings feature two displays pertaining to pressure configuration: Set Pressure and Actual Pressure. The Set Pressure reflects the designated pressure established in accordance with the treatment requirements, while the Actual Pressure provides real-time feedback on the current pressure within the device. An incorporated pressure alarm activates when the preset pressure threshold is surpassed, signaling a warning message on the screen.

4.3.2 Temperature

The temperature inside the device is displayed on the screen with an installed temperature cut-off to turn off the device when the temperature increases. Parameter settings displayed are shown in figure 7(c) and the display screen during treatment is shown in figure 7(e). Mode settings for Single and Dual patients ware shown below in Table

Table 2 Patient Mode and Parameter settings

PATIENT MODE		TREATMENT MODE	PARAMETER SETTING MODE		
Single	Dual		Press (mm Hg)	Temp (°C)	Treat time (Hrs)
Old/new	Old/new				
Patient 1	Patient 1	Continuous	-125	50	48
	Patient 2	Intermittent II	-150	55	60

4.4 Timer

An embedded timer consistently exhibits the elapsedtime on the screen throughout the treatment, facilitating the assessment of both the device's operational efficiency and the effectiveness of the treatment. Timer screen displaying the treatment time and pump life-time shown in figure 7(f)

4.4.1 Treatment Time Totaliser

This feature displays the treatment duration in hours for each patient undergoing therapy during every treatment session.

4.4.2 Pump Lifetime Totaliser

This feature displays the working hours of each pump installed to calculate the working hours and to change in time when it stops working effectively. This feature exhibits the operational hours of each installed pump, enabling the calculation of cumulative working hours. This information proves valuable for determining the optimal time for maintenance or replacement when a pump ceases to operate effectively.

5. Advantages of the Proposed VAC System

This device is unique in various ways that it has novel approach in developing a sustainable, reliable, and an efficient model. Some important advantages of this device are

1. Infection-free isolated circuits
2. High Rate of Wound Healing
3. Low-cost equipment
4. Multi-patient treatment
5. Small in size
6. Less in Weight

7. Low Power consumption

8. Battery backup

9. Reusable Canister

10. High Duty cycle

11. High Durability

12. Digital pressure cut-off

13. Reduce the treatment time

14. Control pumps at different modes.

15. Maintain a digital process

These advancements were done by the studies taken down as dedicated technical pre and post assessment of each trial. Figure 10, presented below, delineates key advantages and advancements within the VAC therapy system.

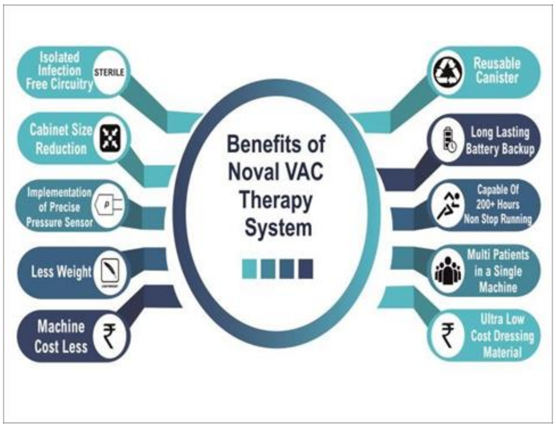

Fig.10. Benefits of Novel VAC Therapy System

6. Practical Experimentation

6.1 Clinical Trials

The Clinical Trials conducted with this isolated dual-patient VAC system studied on, Infection-free treatment, Rate of healing and the Efficiency oftreatment for multiple patients. In this study, 200 patients were subjected to vacuum therapy. Among them 6% of patients are males and 4% are females. Diabetic foot ulcers are located predominantly over the lower and upper extremities of the lower limbs. The efficacy of wound healing is fastened when the infected area is cleared and it is measured by the size of the sequential wound area. The patients under this experimental clinical trials are classified into categories and analysed their wound healing rate based on the condition of their wounds. The Grouping were done on these categories based on their Gender, Age, Mode of treatment, Location of the wound, Type of the wound, Hospitalisation time, and Wound area pre and post- assessment.

6.2 Treatment Procedure

Patients with diabetic foot ulcers should be subjected to the steps as follows: The wound should be thoroughly cleaned and a silicone cup drain tube is to be placed on top of the wound, with the granule foam dressing by sealing it with a drape. The distal end of the suction tube should be connected to a VAC device, which provides a negative pressure of -150 mmHg applied on the wound, either continuously or intermittently for 48 hours. Once

the vacuum is applied, the fluid from the wound is absorbed by the foam and is removed from the wound bed by suction.

Fig.11. Treatment Setup for Patients

The figure 11 above shows the treatment setup for two different patients: 11(a) Diabetic Ulcer at the bottom rear part of the left foot, 11(b) Diabetic Ulcer at the plantar surface of the right feet

7. Results

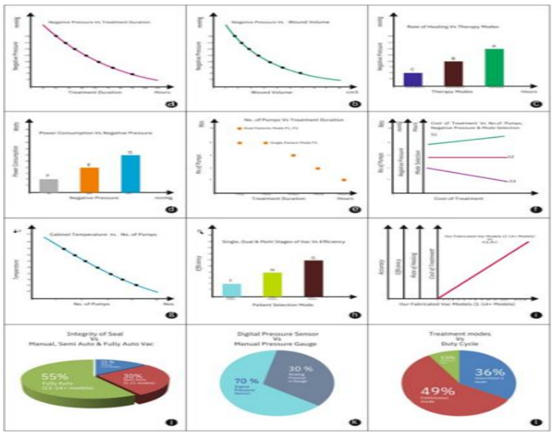

Fig.12. Results of the Treatment Analysis

7.1.1 Treatment Duration

The treatment duration appears to decrease with a concurrent increase in negative pressure through continuous application. Graphical representation of this analysis is illustrated in Figure 12(a) with treatment duration in x-axis and the amount of negative pressure applied y-axis. An observation pertains to the reduction in treatment duration relative to the number of pumps utilized. A positive correlation exists, where heightened pump usage corresponds to an increased duty cycle of the device, subsequently leading to a reduction in treatment hours. This correlation is graphically depicted in Figure 12(e) with treatment duration in x-axis and number of pumps used in y-axis.

7.1.2 Effects on Different Modes

A discernible variation in treatment duration is observed with respect to the modes employed. Each operational mode exerts a distinct influence on the treatment duration. Notably, the continuous mode yields optimal treatment results with a notable reduction in treatment time. This Figure 12(c) shows the rate of healing with the selection of different modes in treatment with therapy mode selected in x-axis and negative pressure applied in y-axis and 12(l) shows the duty cycle of the device with the selection of different modes.

7.1.3 Power Consumption

The device has a remarkable combination of advanced features and low power consumption during treatment. The analysis results depicted in Figure 12(d) effectively showcase the relationship between power consumption and the extent of negative pressure applied withnegative pressure applied in x-axis and power consumedin y-axis. This information holds significant value as it can enhance the device's performance optimization and improve the quality of treatment provided to patients. The Power Consumption analysis for isolated dual patients with different pressures applied in treatment are listed in the Table 3, below

Table 3 Power Consumption for Isolated dual patients

S.No	Patient 1 (Pressure in mmHg)	Patient 2 (Pressure in mmHg)	Total Power Consumption for Dual patients (Watts)
1	~50	~100	17.2
2	~50	~50	15
3	~150	~150	24.4
4	~100	~100	20
5	~150	~100	22.2
6	~150	~50	19.2

7.1.4 Temperature Level

The analysis of the Isolated Multi-Patient VAC system has unveiled an intriguing observation regarding the device's temperature quotient in relation to the numberof pumps employed. Surprisingly, a reduction in the temperature quotient becomes apparent with an increased utilization of pumps. This intriguing relationship is visually depicted in the accompanying Figure 12(g), providing a graphical representation of the inverse correlation between the temperature quotient and the quantity of pumps used with number of pumps used in x-axis and the temperature levels in y-axis. These findings not only contribute valuable insights into the thermal dynamics of the system but also offer practical implications for optimizing its performance by strategically adjusting pump usage.

7.2 Accuracy and Efficiency

The Accuracy of the sensors and efficiency of the device performance are analyzed and the results are shown in the figures 12(h) and 12(i). The figure presented delineates a meticulous examination of the accuracy exhibited by analog and digital pressure sensors employed in the device's development. Notably, the digital pressure sensor exhibited superior performance, demonstrating heightened accuracy in discerning pressure changes. This discerning accuracy underscores the precision and reliability ingrained in the device's design, particularly in capturing subtlevariations in pressure. The efficiency analysis of Single, Dual, and Multi VAC system is shown in figure 12(h) with (selected modes in x-axis and efficiency level in y- axis) high efficiency with Multi VAC systems. Figure 12(i) provides a visual representation of the collective analysis. This figure serves as a comprehensive overview, shedding light on the device's efficacy and functionality through a thorough examination of its performance metrics.

7.3 Rate of Wound Healing

7.3.1 Intensity of Wounds

The analysis of healing rates and the reduction in wound infection is presented in Figure 12(b) with wound volume in x-axis and negative pressure applied in y-axis, depicting the relationship between the level of negative pressure applied and the corresponding reduction in wound site infection. The perfect wound dressing is paramount, necessitating a complete seal without any pressure leakage for an efficient treatment process. Figure 12(j) elucidates the outcomes derived from an analysis conducted during the development of this device. Specifically, the figure presents the results of the analysis pertaining to the integrity of the seal of wounds across various VAC models.

7.4 Reduction of Treatment Costs

The primary advantage of this VAC device lies in its ability to offer high-quality treatment at a low cost. Comprehensive analyses were conducted to assess the treatment cost across various aspects, aiming to establish this device as user-friendly and cost-effective, accessible to individuals with non-healing wounds. The figure12(f) shows various elements employed with the cost of treatment (x-axis) including number of pumps used, level of negative pressure, and selection of modes (y-axis).

A comprehensive examination of the Isolated Multi-Patient VAC system has been conducted, and discussed in table 4, encompassing a thorough analysis of its diverse parameters and establishing standard values for each. This detailed study aims to provide a Comprehensive understanding of the system's performance across various aspects, ensuring adherence to predefined standards and benchmarks.

Table 4 Comprehensive Examination of the VAC system

S.No	PARAMETERS	UNIT	N	MEAN	SD
1	Modes of Operation	Nos	1-3	2	1.414
2	No.of pumps used	Nos	1-16	8.5	10.606
3	Pressure applied	-mmHg	50-200	125	106.06
4	Pressure sensor output optimization	Volts	0.2-4.6	2.4	3.111

5	Achievement of Infection free isolation cases	Nos	1-20	10.5	13.435
6	Temperature during long run	°C	35-55	45	7.071
7	Timers used	Nos	1-8	4.5	4.949
8	Weight	Kg	0.5-14	7.25	9.546
9	Size	Cu.cm	90-60k	30.05k	42.36k
10	Safety alarms	Nos	1-2	1.5	0.707
11	Canister	Ml	30-600	315	403.05
12	Power consumption	Watts	4-300	152	209.30
13	Duty cycle	%	30-99	64.5	48.790
14	Durability/Life	Years	8-10	9	1.414
15	Product Cost	Rs.	5K-2.8L	1.425L	1.945L
16	Dressing material	PPI (pours)	30-45	37.5	10.606
17	Challenge trials	Nos	5-20	12.5	10.606
18	Integrity of Seal	%	80-90	85	7.071
19	Rate of Healing	%	60-90	75	21.213
20	Contradictions/ Wound Severity	%	20-35	27.5	10.606

8 Conclusion

According to the study, using the dual-patient VAC device leads to a higher healing rate and reduced wound severity within a week. The device is proven to have a 100% duty cycle in continuous mode, indicating its effectiveness in treating patients. Additionally, thepower consumption of this device is lower than that of the standard VAC device used for treating a single patient. The dual-patient VAC device is designed with an isolated setup in internal and external circuits, and separate canisters for both patients, ensuring infection-free treatment. The evaluation of the device considered three main aspects of product usability: effectiveness, efficiency, and satisfaction. This device is essential in wound care, providing the best solutions for theproblems faced by standard treatments, thereby ensuring a good quality of life for the patients.

9 Future Scope

India has the highest population of Diabetic patients, among them 15-25% are affected with Diabetic Foot Ulcers including acute and chronic non-healing wounds that mostly lead to amputation. Providing treatment for this growing population can be made easy with this isolated dual-patient VAC system. The aim is to cope with the growing number of patients with Diabetic Foot Ulcers and make treatment available to rural and poor people with quality treatment and high healing rates.

The system is set to include various types of machines such as Dual, Tetra, and Octal. This single machine can treat multiple patients, Furthermore, the system can have a control station for monitoring. This allows Doctors to track treatment progress through a Smartphone Application and adjust the treatment process as needed. Overall this VAC system is an inevitable modality in wound healing treatment to get incredible results changing the lives of patients who are prone to amputation.

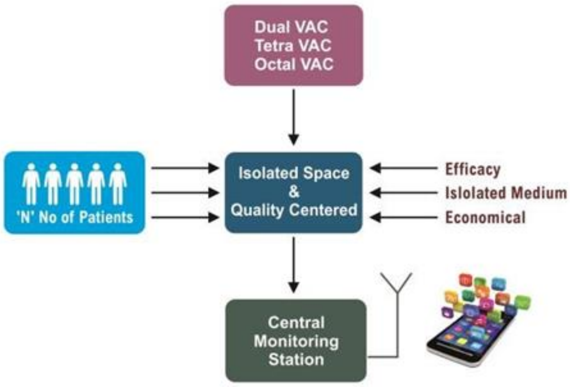

Fig.13. Future Scope

Conflicts of interest

The authors declare no conflicts of interest.

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