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Design and Operation of High Flow Oxygen Therapy: A Novel Approach to Producing High Concentration Humidified Oxygen for Covid-19 Patients

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Abstract

High-flow oxygen therapy provides adequate oxygen to those patients who suffer from pulmonary disorders due to the COVID-19 virus. The purpose of this research is to develop an oxygen therapy device that produces high-flow oxygen and provides a humidified supply of oxygen to patients suffering from Chronic Obstructive Pulmonary Disease (COPD) and Acute Respiratory Distress Syndrome (ARDS) caused by COVID-19. The development of a High-Flow Oxygen Therapy (HFOT) device using cannulation is a much-needed solution to fill the gap in the availability of ventilators in resource-limited settings like Pakistan. The HFOT has a system that offers high-flow oxygen with the help of a blender that is capable of producing a balanced mix of air and oxygen while keeping the fraction of inspired oxygen (FiO_2) at the desired level. A Proportional, Integral, and Derivative (PID) valve is used to control the flow of the mixed gas as per the requirement. The mixed air is then passed through a humidifier that warms, humidifies, and purifies respiratory gas. The flow rate of the device is designed to produce up to 60 Liters Per Minute (LPM) with ± 0.5 variations with proper humidity. The designed prototype is tested for the gas flow rate, oxygen concentration, and desired pressure using professional calibrators and artificial lungs. The test results show significant achievements in delivering humid gases with high flow rates.

Index Terms: *Acute Respiratory Distress Syndrome, Chronic Obstructive Pulmonary Disease, COVID-19, High Flow Oxygen Therapy, PID Control Flow Valve.*

I. INTRODUCTION

The High-Flow Nasal Cannula (HFNC) is a modern and efficient technology that can provide oxygen treatment at a consistent fraction of inspired oxygen (FiO_2) as well as some respiratory support. The capacity of HFNC to satisfy the enhanced ventilator need in individuals with pulmonary problems and subsequently minimize the effort of the respiratory muscles, which is one of the primary physiological benefits over traditional oxygen treatment. The increased patient-reported comfort and acceptance is an important clinical benefit over both Conventional Oxygen Therapy (COT) and Non-Invasive Ventilation (NIV) [1]. There are several reasons for HFNC both within and beyond the Intensive Care Unit (ICU), particularly for moderate hypoxemic patients who are breathing on their own, to prevent extubation failure due to mechanical ventilation [1], and [2]. To keep proper oxygen saturation and breathing levels, respiratory therapies are used. In these therapies, proper alveolar ventilation is crucial for the removal of CO_2 [3]. Nowadays, the supply of air is adjusted during invasive or non-invasive ventilators to achieve appropriate alveolar ventilation. Non-Invasive Ventilation (NIV) increases the inspiratory tidal volume (VT) and maintains appropriate alveolar ventilation [3].

On the other hand, the respiratory disease may be chronic or acute, acute respiratory distress is a disease that lasts only a few days. In contrast, chronic respiratory disease is a continuing problem that steadily worsens over time and needs long-term therapy [4]. HFNC being a new approach has generated a lot of attention due to its easy-to-use feature and feasibility for long-term support. The majority of nations utilize this therapy for COVID-19 individuals as it offers substantially saturated oxygen, and its effectiveness makes it unique and strengthens its specialization. The HFNC provides oxygen with enough warming and humidifying, at a rate of 60 LPM. NIV was favored for long-term home therapy of chronic obstructive pulmonary disease, even though other Invasive Ventilation (IV) devices and Non-Invasive Ventilation (NIV) proved to be highly handy for ventilation. Since they deliver strong pressure to the airways and are hard to synchronize, it might be tiresome and frightening. Contrarily, recently developed HFNC provides an adequate supply of oxygen and is easy to handle [5]. Therefore the advantages of HFNC, as compared to other devices, are easy to use, increased patient tolerance, lower risk of nasal injury, and delivery of oxygen with a high flow rate [6].

HFNC has been employed satisfactorily for adults with acute respiratory distress, and it is now recognized on a global scale as an essential component of hospitals since 2000 [7]. Oxygen therapy using a High-Flow Nasal Cannula (HFNC) was originally utilized in premature newborns and is now often used in critical care units and postoperative patients. HFNC can deliver up to 99% saturated and regulated oxygen during the therapy of acute respiratory distress patients [8]. The use of new technology is widespread in intensive care units these days. Specifically, in ICU where it is used significantly and widely. Particularly in the last few years, the advancement in HFNC made it simpler and easier to operate therefore it is recommended for low-level healthcare setup or personal utilization has opened up new opportunities. Yet beyond this, many things are still to be investigated and further studies would be performed in order to establish better management of severe respiratory disorders or palliative care at home. There is a huge amount of research taking place and lots of new developments are being made on this device every day [9]. This approach appears to be widespread in hospitals in a few years and will be quickly adopted for chronic medical care with various etiologies [10]. Therefore, the aim is to design this novel oxygen therapy device with minimal investment and to bring advancement in the regional medical field as this device is uncommon in South Asia while the world has brought this concept practically. Nevertheless, there have been contradictory findings from reports of its efficacy in intubation avoidance and efficiency improvement in patients with acute hypoxemic respiratory failure. Numerous clinical tests have shown that noninvasive ventilation is ineffective in nearly half of the patients with acute hypoxemic respiratory failure as reported in [9]. Oxygen treatment with HFNC is increasing every day in comparison to oxygen supplied through a facemask. In ICU patients, a 30-minute test indicates an improvement in respiratory parameters through HFNC. Undeniably, HFNC has also been shown to create a certain amount of positive pressure on healthy volunteers and patients [9].

High-flow oxygen therapy with nasal cannulation (HFNC) is a new procedure whose physiological potential benefits have been seen in multiple clinical settings. Invasive Mechanical Ventilation (IV) can produce an even greater gas flow rate and positive airway pressure relative to HFNC, however, it is unpleasant and has several drawbacks like intubation, pain, and can cause infection. In contrast to existing normative approaches, the study primarily attempted to test HFNC in terms of patient satisfaction and dyspnea relief [10]. Although few randomized clinical studies are noteworthy, earlier data on the viability of therapy with HFNC in the therapy of acute respiratory distress primarily comes from an observational study. Earlier studies also contrasted HFNC therapy with less dependable, low-flow devices [11]. However, another drawback of NIV like Continuous Positive Airway Pressure (CPAP) is occasionally ineffective due to poor mask sensitivity since gases can leak from masks and it sometimes hurts patients' faces due to long-term usage. HFNC oxygen delivery is becoming more and more common as a substitute way of supplemental oxygen for severely ill individuals because it reduces the leakage of gases, and is more comforting for patients [12]. Sometimes HFNC is unable to effectively enhance tidal volume (VT). However, it largely benefits COPD patients by decreasing actual dead space and therefore improving alveolar ventilation [13]. That is why it is presumed that HFNC support would be a good complement to nasal Continuous Positive Airway Pressure or CPAP.

In a lung-damaged animal model, partial carbon dioxide pressure ($PaCO_2$) reduced as HFOT flow increased, and $PaCO_2$ fell more effectively with the increased gas release [14]. The effectiveness, safety, and dependability of HFNC treatment have been demonstrated in several observational studies in babies with bronchiolitis. According to recent papers, a wider range of ages and diseases may also be successfully treated through this technique [15]. Improved physiological benefits are thought to be the outcome of HFNC's many benefits over traditional oxygen supply methods. Its usage with severely unwell individuals has been sharply growing substantially during and after post-pandemic COVID-19. It has been used with a wide range of individuals who have different underlying disorders [16]. Warmed and humidified oxygen therapy offers a variety of benefits over conventional oxygen therapy. Using a nasal cannula or similar apparatus, such as a Non-Rebreather Mask (NRBM), oxygen treatment usually delivers cold and dry gas [17], and [18]. This cold, dry gas has the potential to irritate the airways, constrict them, and disrupt mucociliary function, which might have an impact on secretion clearance. Moreover, individuals use a lot of energy to warm and humidify the gas during normal breathing. In this context, heated and humidified oxygen may improve secretions evacuation, lessen inflammation of the airways, and also lower energy consumption, particularly in cases of severe respiratory failure [19].

Acute hypoxemic respiratory failure is a common complication in critically ill patients, which can lead to respiratory failure and require oxygen therapy which is usually treated through a mechanical ventilator. Traditionally, low-flow oxygen therapies and pressure-based ventilators have been used to treat acute hypoxemic respiratory failure patients. In Pakistan, there is currently only one type of High Flow Oxygen Therapy (HFOT) available, which is designed using a venturi-based system. However, the validity of this type of HFOT is still under observation and evaluation. Additionally, it is worth noting that this particular HFOT is relatively expensive, which may limit its availability and accessibility for patients. On contrary, other therapies have their limitations, including inconsistent oxygen delivery and discomfort for patients due to dry airways. Additionally, the COVID-19 pandemic has led to an exceptional surge in demand for ICU ventilators, exacerbating the existing shortage of these resources in resource-limited settings. Therefore, the development of a high-flow oxygen therapy device using cannulation is a much-needed solution to fill the gap in the availability of ventilators in resource-limited settings like Pakistan. The device provides an alternative to traditional low-flow oxygen therapies and pressure-based ventilators, making it a valuable addition to ICU equipment. Additionally, the hospital in Pakistan is in need of a device like HFOT in huge quantity in order to treat patients with COVID-19 and similar pulmonary diseases. Therefore, the goal of this study is to develop a High-Flow Oxygen Therapy (HFOT) device. This innovative device will be used to provide non-invasive respiratory therapy for patients with pulmonary diseases such as COVID-19, with warm, humidified, and oxygen-enriched mixed gas. The mixed gas with oxygen will be provided at a high flow rate using a nasal cannula. This high-flow oxygen therapy device will be capable of providing effective treatment for Acute Respiratory Distress Syndrome (ARDS) patients as well. Thus, this device will inexpensively fill the gap.

II. PROBLEM STATEMENT AND ITS PROPOSED SOLUTION

A. Problem Description

The emergence of COVID-19 as a pandemic in December 2019 has resulted in a high number of patients developing Acute Respiratory Distress Syndrome (ARDS) and pneumonia. Standard mechanical ventilation and pre-existing NIV techniques have not been effective in treating these patients, leading to a high mortality rate. As a result, the need for high-flow oxygen therapy has become crucial due to the fact that low-flow oxygen therapies are unable to deliver the necessary amount of oxygen required by these patients. In Pakistan, there is a lack of development for devices capable of delivering the required amount of oxygen, which has led to an urgent need for more effective oxygen therapies to address the situation. HFOT provides high-flow oxygen in an appropriate environment, so this device proved to be lifesaving in this global pandemic. COVID-19 appeared to be a nightmare for the entire world. It harms the lungs and badly impairs the health of the individual. COVID-19 may cause acute respiratory distress and render the patient unable to breathe properly. This condition could ultimately cause the death of a person.

B. Solution Framework

Since HFOT has grown in favor among intensivists caring for patients with acute respiratory failure during COVID-19 in developed countries. Therefore, the proposed solution to the above problem is high-flow oxygen therapy (HFOT). Additionally, the hospitals in Pakistan are facing difficulties to treat patients with pulmonary disease due to the insufficient number of devices capable of supporting long-term lung therapy. Therefore, this device will inexpensively fill this gap. This article concentrates on the design and operation of the HFOT.

III. METHOD AND MATERIAL

A. Blending of Gases

The first stage involves the regulation of primary pressure through the use of a single-stage medical gas supply. This ensures that the pressure of oxygen is maintained within the optimal range of 3 to 5.5 bar, while the air pressure is controlled within the range of 2.83 to 5.2 bar.

After the pressure regulation, an air/oxygen blender has been used. The air/oxygen blender is utilized to achieve a highly accurate and precise blend of oxygen with the air. The blending device is capable of generating oxygen concentrations between 21% and 100%, allowing healthcare professionals to tailor the oxygen concentration to the individual needs of the patient.

B. Flow Regulation

The controlled pressure was obtained from the blender, yet the flow is to be regulated so the flow regulator PID valve is chosen for this function. A control circuit is designed to control its opening; the opening of the valve is directly proportional to the input voltage. As the voltage of the PID valve raises the flow of the gases through the valve also increases, thus, resulting in a regulated flow along with secondary regulated pressure. At this point, the flow rate is 1 LPM-60 LPM and the pressure is 5 cm H_2O-40 cm H_2O. In addition, the monitoring of FiO_2 is also required, this is done through a flow sensor and Arduino [20]. The flow sensor (occasionally called a "flow meter") is an electrical device that monitors or controls the rate at which gases flow.

C. Warming and Humidification of Gases

After the flow regulation, the next step is to warm and humidify the mixed gases. For this purpose, the mixed gases are then shifted into the water chamber. The water chamber maintains the water level at a preset volume. The water is warmed by the heater plate creating a high concentration of water vapors in the headspace. The air flows through the chamber and collects water vapors, which in turn humidify and warm the gas mixer. The water chamber is connected to a heated inspiratory circuit which contains a digital temperature and humidity sensor DHT11 [21]. The temperature and humidity detected by the sensor are transmitted to Arduino for monitoring. When the temperature rises to the setpoint, the control algorithm programmed in the Arduino turns off the heater and when the temperature falls below the setpoint, it turns on the heater. Thus, this sensor is used to ensure that the temperature and humidity of mixed gases are at the desired level.

D. Deliverance of Oxygen to the Patient

Finally, the device delivered oxygen to the artificial lung through the patient circuit and nasal cannula to ensure efficient and effective oxygen delivery. The patient circuit is a closed circuit that includes the device, tubing, and nasal cannula, ensuring that oxygen is delivered directly to the patient and minimizing the risk of gas leakage.

E. Validity and Reliability

The device parameters for testing are defined by considering the flow rate from 0-60 LPM. The oxygen concentration or FiO_2 is from 21% to 100%. The flow rate of the device is aimed to check with the professional 4070-flow analyzer [22]. This ensured that the device is capable of regulating oxygen and air with the desired setting. Additionally, the data collected would be reliable and can be used in future research studies.

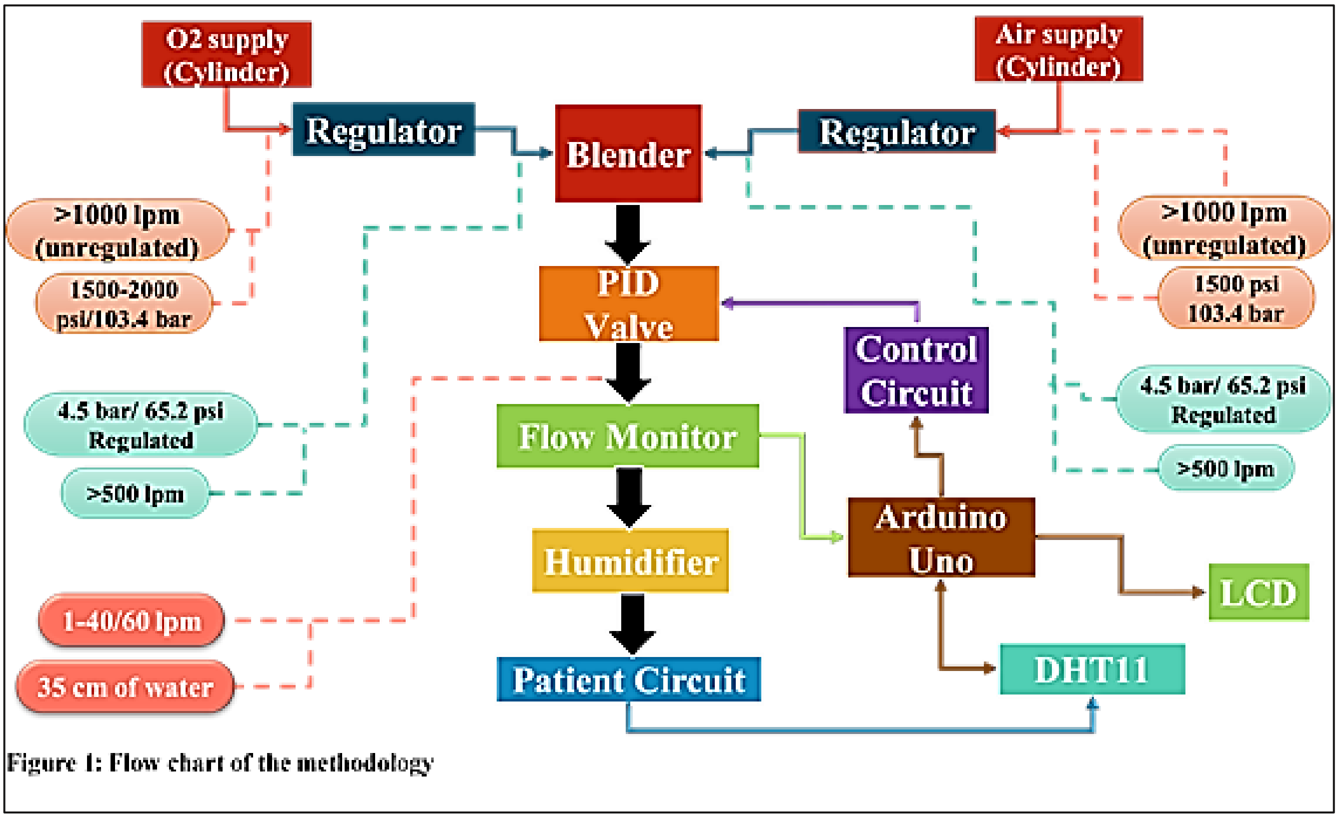

Figure I: Flow Chart of Methodology

IV. RESULTS

As discussed in the previous section, the prototype device is tested for each parameter set during the design process. In this section, each test is explained in detail.

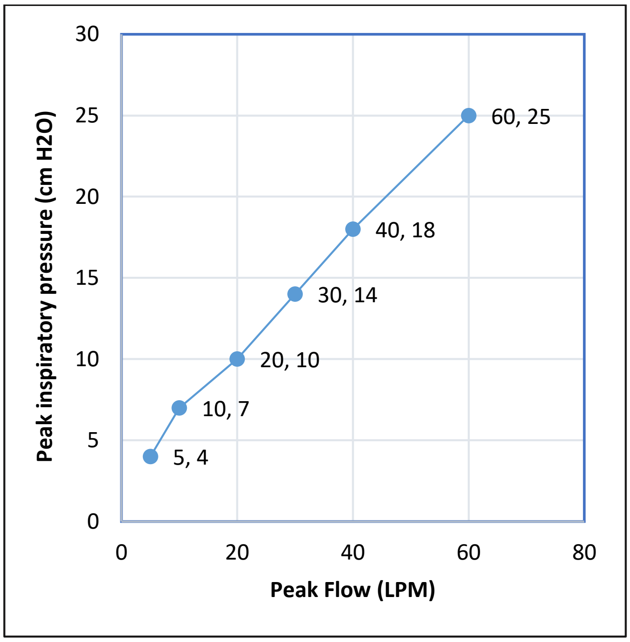

Figure II: Peak Inspiratory Pressure Vs Peak Flow in HFOT

A. *Peak Inspiratory Pressure and Peak Flow Test*

Figure 2 demonstrates the connection between peak flow and peak inspiratory pressure. Peak Inspiratory Pressure (PIP) refers to the pressure that is applied to the lungs during inhalation [21]. The positive water pressure is measured in centimeters for mechanical ventilation (cm H_2O). It can be seen in the graph of figure II that when 4 cm H_2O pressure was applied, flow increased to 5 LPM, and as pressure increased, flow also increased. When the pressure was raised to 7 cm H_2O, the device flow increased to 10 LPM, and when the pressure reached 25 cm H_2O, the desired flow of 60 LPM was acquired. These results were obtained using a pressure gauge for pressure measurement and a flow sensor for flow measurement.

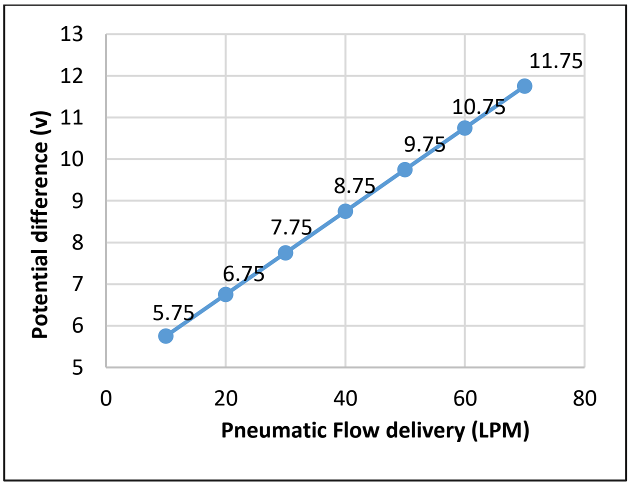

Figure III: PID Valve Voltage Difference and Flow Rate in PID Valve

B. *PID Valve Flow Rate Test*

The PID valve requires 5v (Voffset) to operate and any additional voltage on top of Voffset will trigger the valve. In order to determine the valve relationship between the PID valve operating voltages and flow rate, a test bench has been set up to provide voltage to the PID valve and verify the flow rate of the valve. Figure III illustrates the relationship between the PID valve potential difference and the flow rate obtained from this experiment. Initially, the valve didn't permit the flow until the input voltage reached 5.75 V. At this point, the valve opened and a flow of 10 LPM is recorded. From this point, onward a step size of 1 V is applied and the flow rate is recorded on each point as shown in figure III. As the voltage further increased to 6.75 V the flow rate became 20 LPM. Thus, each volt increase in the input voltages results in an increase in the flow rate of about 10 LPM. And a maximum required flow rate of 60 LPM has been achieved at an input voltage of 11.75 V. Which is the primary objective of designing the device. These results are recorded and verified using a laboratory voltmeter and 4070-flow analyzer.

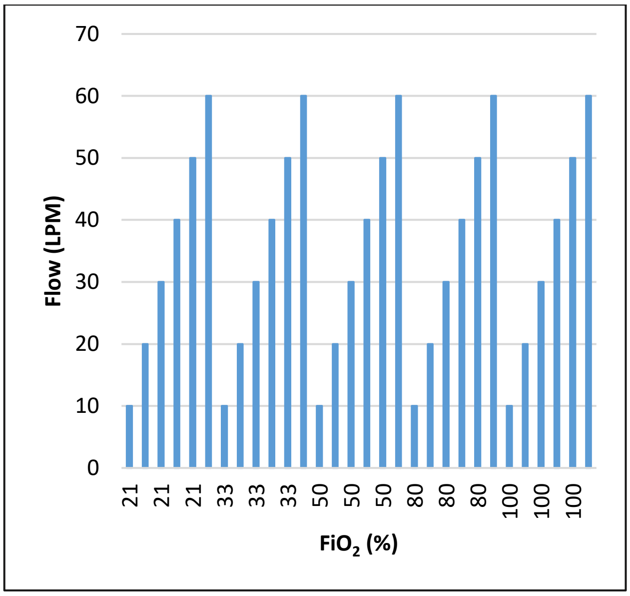

Figure IV: Flow and Preset FiO_2 Concentration after Blending Medical Gases

C. Oxygen Concentration Test

After maintaining the flow rate and pressure, obtaining the correct oxygen concentration is vital for the operation of the device. Therefore, the device is tested for the oxygen concentration in gases mixer after blending oxygen with the air. Figure IV shows the results of the oxygen analyzer at the flow rate of 10 LPM to 60 LPM [23]. And it is evident from the results that the device is capable of producing the set specific value of FiO_2 concentration in the proportional mixture regardless of the flow rate. The blender is tested on different oxygen concentrations (i.e. 21%, 33%, 50%, 80%, and 100%). These results are verified multiple times using an oxygen analyzer.

D. Humidity and Temperature Test

The mixed gases are required to be warmed and humidified before entering the patient circuit of the device. That is why a Peltier [24] embedded with a DHT11 sensor (temperature and humidity sensor) is used for this purpose. The test for the time required to warm the chamber containing a specific amount of water is noted in order to maintain the required parameters of humidity and temperature. From the experiments, it has been noted that there is only a 5^0C rise in the temperature for the first 30 seconds of operation when the room temperature is about 20^0C. The device consumed around 120 seconds to reach a temperature of 37^0C. In order to maintain the desired temperature, a switching relay is employed and controlled through the Arduino using the control algorithm. The device using a control algorithm is capable of producing the mixed gases at a temperature of 37^0C with 100 percent relative humidity.

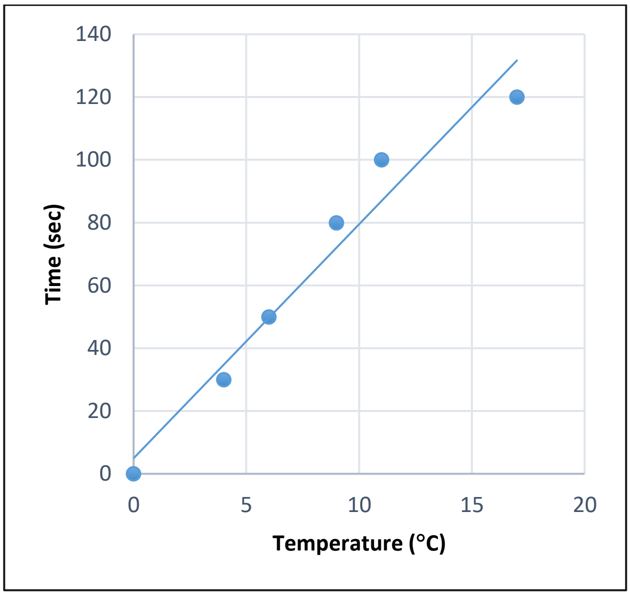

Figure V: Time and Temperature Relationship of Humidifier

V. DISCUSSION

Notably, in 2022 Sebastiano Maria Colombo examined these effects in all patients whose HFNC treatment was effective after 2 hours and was confirmed at daily monitoring [19]. Due to the varied delivery methods, low-flow oxygen therapy can only provide up to 20 LPM whereas a high-flow nasal cannula can provide up to 60 LPM [25].

Many patients with pulmonary distress are treated by professionals using non-invasive respiratory aids, such as HFNC. During the most recent COVID-19 epidemic, within the ICU, Franco and Guy, examined the viability and therapeutic effects of non-invasive respiratory supports NIV, HFNC, and CPAP. The use of HFNC in hypoxic patients was found successful, according to the authors, which lessens the effort for already overburdened ICUs [18]. The formation of airway obstruction and the blockage of fluids may be prevented by high flow rates of heated and humidified oxygen. These features contribute to the understanding of why people with severe lung disease tolerate the device particularly well. Utilizing nasal high flow after extubation increased oxygenation compared to using Venturi mask oxygen therapy with the equivalent set FiO_2. Reduced patient discomfort, fewer desaturations and contact separations, and a lower reintubation rate were also associated with it.

This study used a cannula instead facemask in this device, as cannulation is preferred in case of severe hypoxia for delivery of supplementary oxygen [26]. This device is flow-based, in contrast to CPAP and BiPAP which are pressure-based and deliver low flow as compared to HFOT. The HFOT is a high-flow device that can deliver high flow when a patient's respiratory system is severely affected by COVID-19. It has been suggested that using HFOT improves gas exchange by decreasing upper airway dead space and reducing resistance [27]. Compared to CPAP, HFOT is believed to be less intrusive, more appreciated by individuals, and simpler for staff to administer [28]. In numerous experiments, it has been shown that HFOT is more successful than conventional treatments such as CPAP or Low-Flow Oxygen Therapy (LFOT) [29]. The extensive use of this type of Non-Invasive Respiratory Support (NRS) in most institutions recently, especially in immature babies, is due to improved tolerability, greater movement, stronger bonds between the infant and mother, and less nasal injury from HFOT [30]. Numerous professionals were ill during the COVID-19 epidemic, increasing concerns about the use of aerosol-generating techniques. It appears that the insert of the tube is being presented as a consequence. The empirical evidence supporting the generation and distribution of bioaerosols with HFOT is presented here and shows that there is less risk than conventional respirators. To aid hypoxemic COVID-19 patients and prevent intubation, it may be possible to use HFNC prongs with a face mask over the patient's face [31].

The globe is currently witnessing a pandemic brought on by a deadly mutant coronavirus (COVID-19), and the worldwide health sector is facing an unusual financial crisis. The most frequent associations include cold, coughing, breathlessness, muscle aches, fatigue, and pneumonitis. The mainstay of therapy for hypoxemic respiratory failure is supplementary oxygen therapy. HFOT is a novel non-invasive method for enhancing ventilation and oxygenation in severely ill individuals. HFOT can minimize respiratory support in this dire situation [32]. HFOT can reduce the requirement for intubation, the length of stay in the intensive care unit, and issues with mechanical ventilation in patients with COVID-19. HFOT also benefits individuals who experience apneic hypoxemia while maintaining airway control. HFOT devices need to be installed in a single space. A highly effective high-flow oxygen treatment is HFOT.

This research aimed to develop HFOT for patients suffering from COPD and ARDS caused by COVID-19, using cannulation. This device is designed to provide high-flow oxygen, in contrast to the low-flow oxygen therapies and pressure-based ventilators traditionally used to assist ARDS patients. The novel device utilizes a low-cost sensor with adequate accuracy and a reliable flow sensor in comparison to a venture-based flow sensor which is used in similar devices. From the results, it can be concluded that patients with mild to severe ARDS can receive high-flow oxygen from the device up to 60 LPM. The oxygen concentration remained remarkably steady and was unaffected by changes in the flow rate, even when the flow was increased from 10 to 60 LPM during the experiments. Although the HFOT did not have a substantial impact on gas exchanges directly, due to its high flow and oxygen-rich warm and humid air it will improve comfort, dyspnea, and respiratory rate.

The device was subjected to rigorous testing to ensure its accuracy and effectiveness in delivering high-flow oxygen therapy to ARDS patients. A 4070-flow analyzer was used to measure the device's accuracy in delivering a consistent flow of oxygen to patients. The data collected from the flow analyzer confirmed the device's high level of accuracy in delivering a stable flow of oxygen, even at high flow rates.

The findings of Ali et. al [33] study revealed that there is a significant gap in the availability of ventilators in Pakistani ICUs. The study found that only a small percentage of ICUs in Pakistan had access to ventilators, highlighting the urgent need to address this gap. The development of a novel high-flow oxygen therapy device using cannulation, as described in the previous paragraphs, represents a promising solution to address the gap in ventilator availability in Pakistan due to low prices and good results [33]. Moreover, due to the COVID-19 pandemic, Pakistan is facing a severe financial crisis in the construction industry. So, it might not be feasible to invest in the immediate development of new expensive oxygen therapies [34-37].

VI. CONCLUSION

This research presented a High-Flow Oxygen Therapy (HFOT) device that is the most recent technology that delivers a high flow of oxygen mixed with air at the required oxygen concentration level and flow rate. The mixer of oxygen and air is also undergone a humidification and warming process to reduce the dryness and itching of the pulmonary tract for long-term usage. As evident by the earlier research, the cannulation of HFOT also reduces the need for intubation. The device shows excellent results for the pressure, flow rate, humidification, oxygen concentration, and temperature maintenance of the gases during the experiments. The designed device is capable of producing FiO_2 from 21% to 100% with a flow rate of 10 LPM to 60 LPM. Also, relative humidity of up to 100% can be achieved at 37^0C with the device. In conclusion, it is clear that the HFOT device developed will be a light in the dark for individuals experiencing severe breathing difficulties who cannot afford the expensive, high-demand, and limited available ventilators, especially in underdeveloped countries like Pakistan.

The future direction of the research is to design an embedded compact system with battery backup features. Also, it is recommended to add a touchscreen feedback display for an easy interface. Furthermore, the device may be recommended for clinical trials, real-time monitoring, and data collection, exploration of potential uses beyond ARDS, and efforts to increase access in resource-limited settings. These efforts can help ensure that the device continues to improve the management of critically ill patients and save lives.

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Authors Contributions

The contribution of the authors was as follows: Sarmad Shams's contribution to this study was the concept, technical implementation, methodology to conduct this research work, project administration, and correspondence.
The rest of the authors jointly perform all the tasks, i.e., data collection, supervision, compilation, paper writing, and validation.

Conflict of Interest

The authors declare no conflict of interest and confirm that this work is original and not plagiarized from any other source, i.e., electronic or print media. The information obtained from all of the sources is properly recognized and cited below.

Data Availability Statement

The testing data is available in this paper.

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