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DEVELOPMENT AND PROTOTYPING OF CONTROLLER MECHANISM OF MECHANICAL VENTILATOR AND ADAPTATION FOR PEDIATRIC UTILIZATION

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Abstract: Key medical equipment that is needed for effectively dealing with critical patients arising from COVID-19 infected patience is the Mechanical Ventilator. When the lungs are so damaged that a patient is not getting enough oxygen or exhaling carbon dioxide, the ventilator is used. A prior mechanical ventilator design did not incorporate mechanically adjustable inspiratory to expiratory ratio but through the use of electronic circuit boards and numerous central processing units (CPU) and sensors which often fails during use. In addition, most mechanical ventilators are either designed for adults or children; but not both. In Nigeria, electrical power supply to ensure uninterrupted power supply can be a challenge due to epileptic power supply from the utility companies. This paper presents the results of the development and prototyping of an electrically powered cam-actuated mechanical ventilator .mechanism for adjusting the inspiratory to the expiratory ratio (I/E) in the range 1:2 to 1:3. A breadth per minute of 12 to 25 was achieved after experimentation. This is expected to provide adequate breaths per minute (bpm) for the critical care of a COVID-19 patient. A careful design of the structural supports was able to interchangeably admit AMBU bags for pediatric use and adults. This adaptation eliminates the need for providing an independent mechanical ventilator system for adults and children. A modern sense approach and automatically activate other sources of electrical power to keep the mechanical ventilator running was explored for guaranteed performance during service.

Keywords:* *Cam, Corona Virus, Charge Controller, Concentric Rings, Respiration, Solar Power and Ventilator

1. Introduction

The need for mechanical ventilation is a common feature of the patient requiring admission to the intensive care unit (ICU) in hospitals. There are many uses for a mechanical ventilator. This can be in form of a patient's suffering from cardiac arrest, a tired asthmatic patient in need of assistance, or a victim of multiple traumas who has been pharmacologically paralyzed. However, all of these reasons may be broken down into one category, acute respiratory failure where the partial pressure of oxygen in the arterial blood (PaO_2) is less than 60 mm Hg on 50 % oxygen and/or partial pressure of carbon dioxide in the arterial blood ($PaCO_2$) is greater than 50 mm Hg with a pH less than or equal to 7.25) (Pereira et al., 2020).

One of the consequences of Coronavirus disease 2019 (COVID-19) is the result of an infection caused by severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) (To et al., 2020; Zhu et al., 2020). COVID-19 pandemic not only transcends individual impact but also has major consequences for many national healthcare systems in the world with about 4,294,895 deaths globally out of about 202,608,517 (Worldometer, 2021). The degree of the widespread outbreak causes enormous pressure and increasing demand for ventilation equipment that may prevent high mortality rates. The number of patients needing invasive mechanical ventilation has surpassed several high-income countries' installed capacity (Pereira et al., 2020).

The ley medical equipment that is needed for effectively dealing with critical patients arising from COVID-19 infected patience is the Mechanical Ventilator. It is an automated machine in which energy is transmitted or transformed (by the ventilator's drive mechanism) in a predetermined manner (by the control circuit) to augment or replace the patient’s muscles in performing the work of breathing. When the lungs are so damaged that a patient is not getting enough oxygen or exhaling carbon dioxide, the ventilator is used to keep the patient alive.

The general-purpose-type mechanical ventilators used in the 1980s worked on simple operating principles with few circuit boards and/or sensors for its control (Richard & Kacmarek, 2009). These old model mechanical ventilators were rugged and did not break down easily. Operator error accounted for most of their sudden malfunctions (Vignaux, Tassaux, & Jolliet, 2009; Yoshioka, Nakane, & Kawamae, 2014). However, technological developments over the past decades have led to significant improvements in the performance of mechanical ventilators through the use of electronic circuit boards and numerous central processing units (CPUs) and sensors.

These modern mechanical ventilators have more failure points that increase the likelihood of a breakdown. A prior mechanical ventilator design did not incorporate adjustable inspiratory to the expiratory ratio (Al Husseini et al., 2010). To overcome this problem another design employed the pressure-controlled emergency mechanical ventilator (Pereira et al., 2020).

Medical mechanical ventilators are normally sophisticated machines for general use It is then important that an emergency invasive mechanical ventilator design emphasizes simplicity and local availability of components and manufacture, while simultaneously providing effective and safe ventilator support., although this level of sophistication is not needed to save lives. Indeed, several governments have issued guidelines for simplified mechanical ventilators for COVID-19. A major objective of this paper is to develop and fabricate an electrically powered cam-actuated mechanical ventilator .mechanism for adjusting the inspiratory to the expiratory ratio (I/E), tidal volume ad breadths per minute.

A cheap means of providing positive pressure ventilation to patients who are not breathing or not breathing adequately is the use of a bag valve mask (BVM), sometimes known by the proprietary name Ambu bag or generically as a manual resuscitator or "self-inflating bag" in preference to mouth-to-mouth ventilation. When the mechanical ventilator machine is cam-actuated for BVM compression, the structural support for the BVM used for adults will deliver air volume displacement that may be too excessive for children. Another objective of this paper is to fabricate structural support that will not only accommodate BVM for adults but also children.

Another challenge in using a mechanical ventilator for ICU patients is an electricity supply to keep the ventilator running using various types of power sources. One of the objectives of this paper is to explore various means of ensuring that the power supply to the ventilator never stops; by taking into account the epileptic nature of the power supply in some developing countries like Nigeria.

2. MATERIALS AND METHODS

In this study, the principles of concurrent engineering will be applied, where the design of products and processes are integrated into parallel. The following stages of the method are; (1) definitions, (2) conceptual design, (3) detail design, and (4) materialization design. The conceptual flowchart based on the concurrent engineering principle is shown in Figure 1.

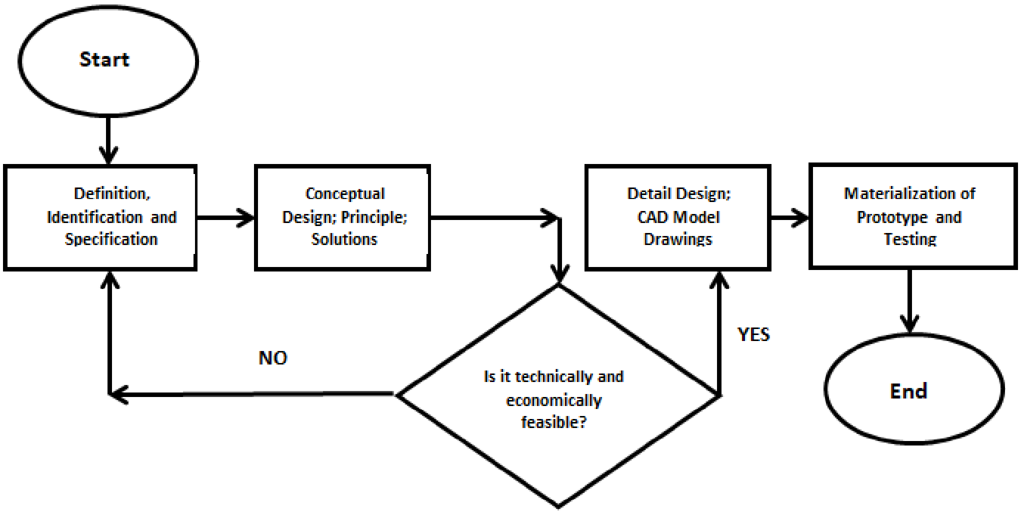


Figure 1 : Conceptual flowchart of design of products, processes, and materialization of prototype

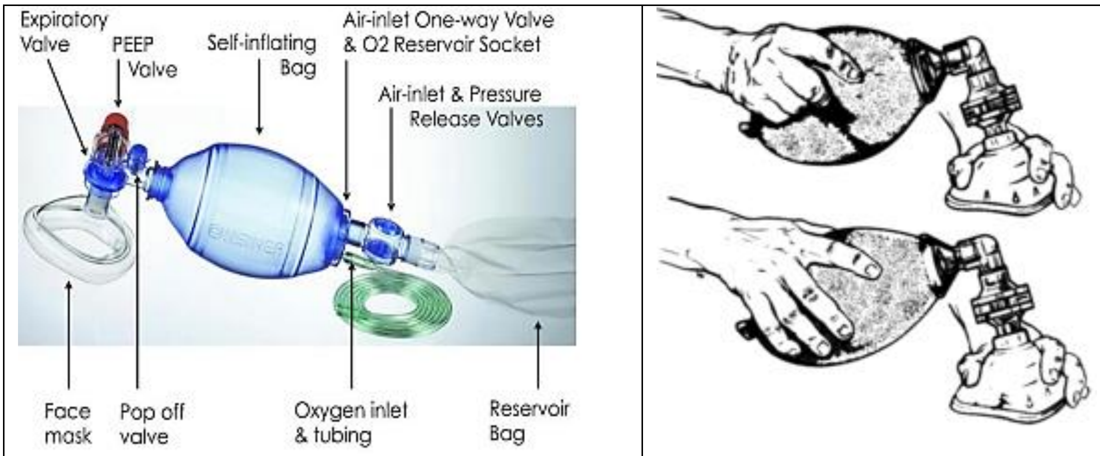
2.1 Requirements and Specifications

A typical COVID-19 patient arriving at a hospital will feel weak and suffering from impaired breathing. After some time, the patient's lungs and airways become compromised with mucus build-up and general weakness if no serious care is provided. This will require the patient subjected to anesthesia and intubated to allow for a mechanical ventilator to be connected assisting in breathing.

The ventilator is connected to the patient through an endotracheal or ET tube that is placed into the mouth or nose and down into the windpipe (intubation) or a surgical hole placed in their neck and a tube (tracheostomy or "trach" tube) is connected through that hole. The ventilator blows gas (air plus oxygen as needed) into a person's lungs to do all of the breathing or just assisting the patient to breathe. In this study, the design principle of a low-cost portable automatic mechanical ventilator will be based on the simulation of hand muscles' biomechanics to provide repetitive compression and self-inflation of the bag valve mask (BVM) manual resuscitator as shown in

Figure 2 (a) and

Figure 2 (b).



(a) (b)

Figure 2: Design principle based on (a) Ambu bag or BVM (Hossain, Halder, Al Aman, Islam, & Rahman), (b) ergonomic of hand-operated BVM

This study will utilize the results of the evaluation of the limitations of hand-operated BVM that gave the medium gripping strength of the hand squeezing the BVM between 196 and 392 N as the most likely grip strength by health physicians (Khoury et al., 2016). Among the several methods of actuation to replicate hand-actuated BVM, the methodology adopted by this study is to use the hinged BVM compressor lever and oscillating disc cam-roller follower mechanism based on the space diagram in

Figure 3. The hinged compressor lever arm has two ends with end A compressing the BVM, while the cam mechanism provides the timed lift force at lever end B through a vertical distance of the follower as used in the literature of similar studies (Al Husseini et al., 2010; Alaci, Ciornei, Siretean, & Ciornei, 2018).

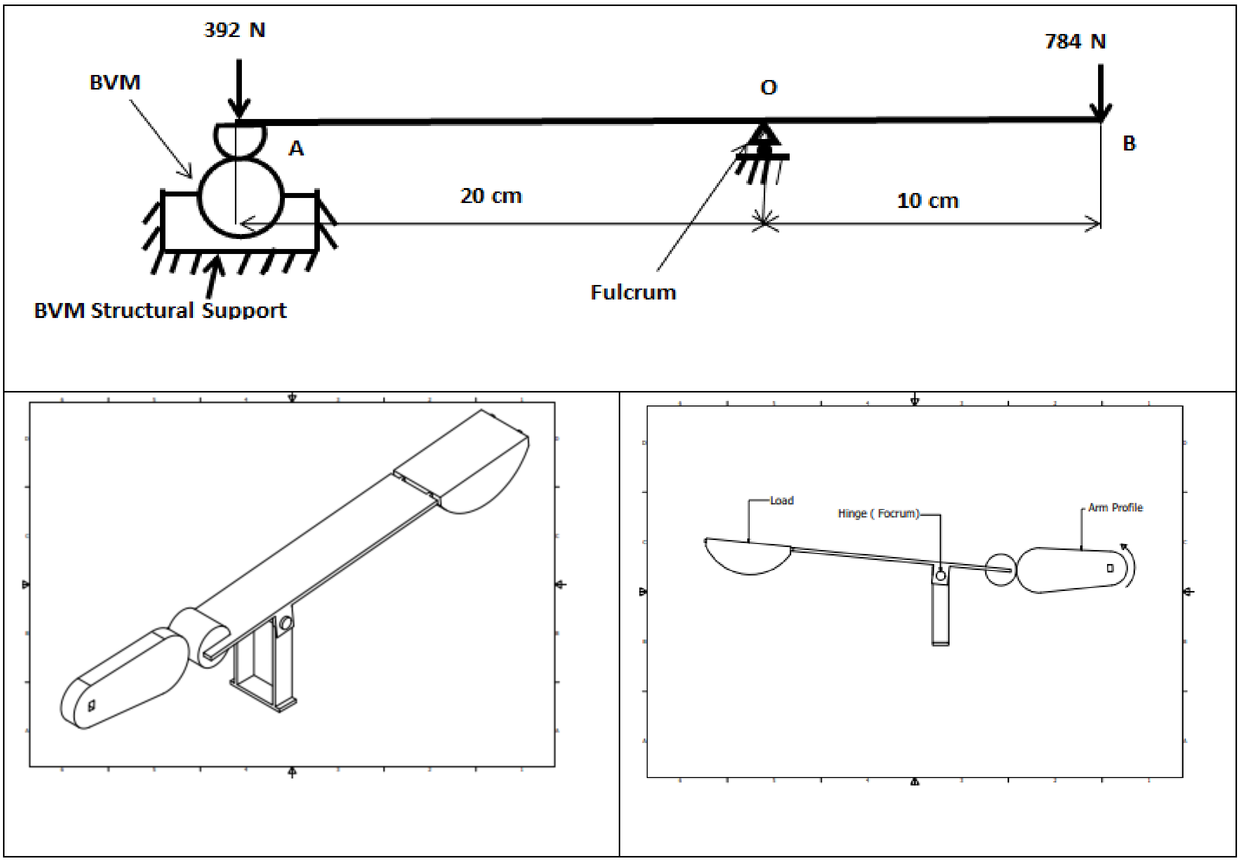


Figure 3: Space diagram depicting the kinematics of the design concept

The contact point between the compression lever and the BVM bag can vary through a vertical distance is incorporated into the breathing cycle as; (1) Inspiration phase (sum of, (2) Expiration phase, and (4) Pause phase (Domènech-Mestres, Blanco-Romero, de la Fuente-Morató, & Ayala-Chauvin, 2021). If the inverse of the breathing frequency in cycles/min is t_c in seconds, the literature study of the concept of parametric breathing cycle has established that:

i. The inspiration phase is $25\%\ of\ t_c$
ii. The expiration phase is $50\%\ of\ t_c$
iii. The pause phase is $25\%\ of\ t_c$

In this study, the inspiration phase was determined to take place in 4 seconds of airflow at different mechanical loads during pressure control ventilation as obtained in the study of (Hess, 2014). This gives the expiratory phase time of 8 seconds and pause phase of 4 seconds to give inspiration to expiration ratio of 1:2 for adults. The Ambu oval silicone bag used in this study is for both adults (Length/Diameter of 212/131 mm) and pediatrics (Length/Diameter of 146/100 mm) with the adult version producing breathing patterns that mimic the way we normally breadth during our usual living activities.

2.2 Structural Supports

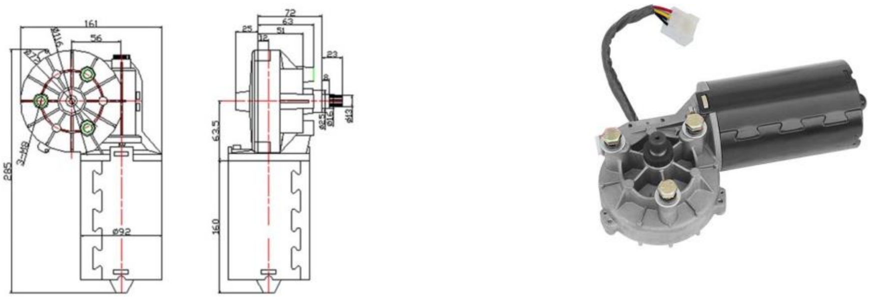
The core materials used for structural supports of the prototype in this research consisted mostly of mild steel (lever/follower and cam/motor supports), wooden supports (big BVM bag), and PPMA support (small BVM bag). These are to ensure that appropriate supports and housing are provided for the Ambu oval silicone BVM bag housings for both adult (Length/Diameter of 212/131 mm) and pediatrics (Length/Diameter of 146/100 mm) that can resist a compressive force of about 392 N as shown in Figure 3. The vertical wooden supports are rigidly held on a flat wooden base with further extension to provide a base for the metallic supports for the disc cam motor/cam and roller follower/Ambu compression arm. Given the dimensions of the Ambu bag for pediatrics and adults, the entire frame for the smaller structure is made to fit snugly into that with bigger dimensions. Flat plate supports made from mild steel are rigidly held on the horizontal wooden frame to provide vertical pin-joint support for the cam motor/cam and hinged-joint support for the roller follower/Ambu compression arm.

2.3 Dynamics of compression and self-inflation of BVM bag

In providing the required force to compress the BVM bag, this study will utilize a machine element having a curved outline which by its rotation motion will give a predetermined specified oscillatory motion to provide a lift to another element called the follower at the end of the lever arm B as shown in **Figure** 3. If the maximum angular displacement of the follower about the hinged support is not to exceed 38^{o} and the vertical lift of the follower is limited to 53.0 and 38.0 mm for the big and small BVM bag respectively, then the work required to provide the follower lifts are 41.6 J and 29.8 J. In determining the torque to be provided by the prime mover, the work done in rotating the cam is equated to the work done in lifting the follower about the hinged supports as shown in the equation below.

$$T\ (Torque)\ .\ \theta\ (change\ in\ angle\ turned\ by\ cam\ to\ raise\ the\ follower) = F(Lift\ force)\ \ .\ Y(change\ in\ follower\ vertical\ lift)$$

If θ is 289^{o} (or 5.045 radians), F is 784 N, Y is 0.053 m, then T will give 8.24 N-m. In this study, a vehicle windshield 12V/24V DC wiper motor with a speed of 25/48 rpm, the torque of 5/25 N-m and 49/50 W power is provided to give the necessary power of 41 W (Torque x angular velocity) required to run the cam, lift the follower and compress the BVM bag as shown in **Figure 4**.



(a) (b)

Figure 4: Automobile windscreen wiper motor, (a) Side view; (b) isometric view of the wiper motor

2.3 Design of cam and oscillating roller follower mechanism

In this study, the design is based on the CAM principle having some additional features of precise mechanical control, battery and solar power operated cam motor mechanism for pediatric and adult models. This is obtained by slightly changing the diameters of the roller follower for different applications such that air volume delivered was measured as a function of cam angle by integrating the flow rate over time (Al Husseini et al., 2010). The typical roller radius considered for use in this study is; R1=3.5mm, R2=8.0mm, R3=12.3mm, R4=15.0mm, and R5=17.5mm. These are expected to give different follower vertical lift heights for each roller radius to give different desired air.

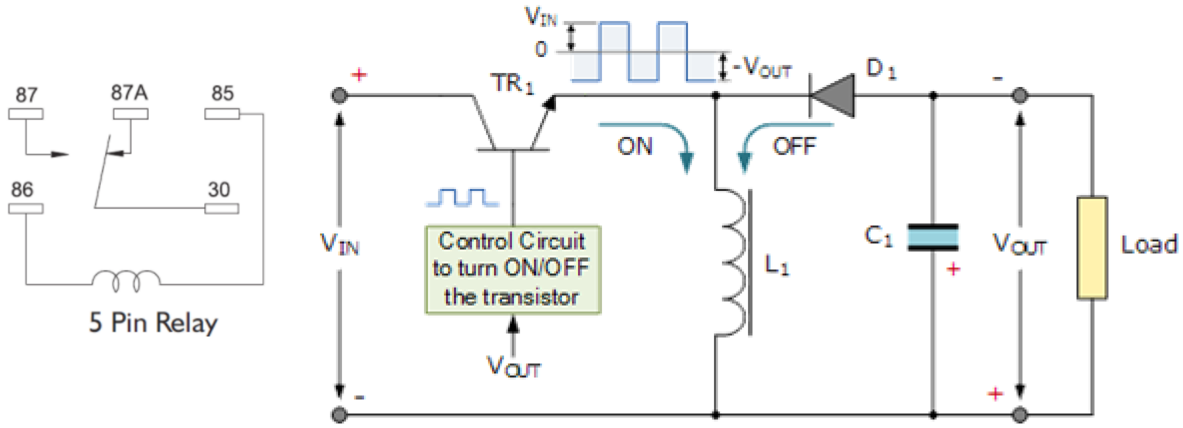
The shafts of the 12 V DC motor are rigidly attached using a coupling that was force-fitted at one end while the other end is connected to one end of the disk cam that rotates according to motor direction. When the motor rotates, the torque created by the disk-cam lifts the follower and lever at end B about the fulcrum to a particular angle as shown in

Figure 3 with the mechanical arm at end A to provide a compression tension of the BVM bag.

The challenge is to determine the cam profile suitable to generate the desired motion of the follower rise function defined as the displacement of the follower with change in the cam rotation where the desired output motion of the follower is already known for every cam rotation angle. In this study, the graphical approach will be used since the default settings on many cams analytical design software assumed that the cam and follower will always remain in contact, which means that no chattering is allowed. The parameters used in this study are: maximum angle of follower lift is 38^o, base circle radius of the cam is 38 mm, and eccentricity of 100 mm, number of sections according to movement law is 3. From these parameters, the design process of the mechanism has been carried out, to obtain the corresponding cam profile to be manufactured and checked if the cam curvature was appropriate to ensure good performance. The profile of the designed cam consists of two arcs of circles and two small tangential flanks that join them.

2.4 Design of electrical power switching circuit

The power source for the electric motor used on the mechanical ventilator in this study consists of a 12 V DC power supply to continuously run the electric motor and deliver air and/or gas to the patient will be a 240 V AC to 12 DC power converter delivery to power the ventilator directly from a wall outlet or a vehicle inverter in Figure 5 (a). When external power is unavailable, a 5-pin switching relay is used to switch power between the AC/DC converter and the 12 V DC solar power source circuits. To effectively manage the supply voltage from the battery, a Buck-Boost switching regulator circuit is provided (Licea, Pinal, Gutiérrez, Ramírez, & Perez, 2018; Shiau & Ma, 2013; Shiau, Ma, Yang, Wang, & Gong, 2009) as shown in **Figure 5** (b).

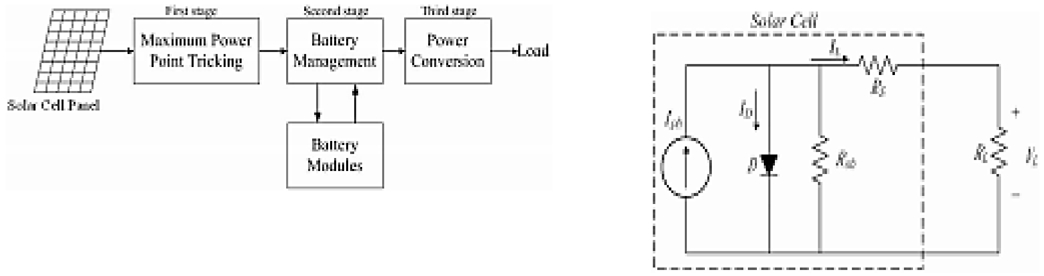


(a) (b)

Figure 5 : Electrical Circuit for (a) 5-pins switching relay, and (b) Buck-Boost switching regulator circuit

The buck-boost regulator is known to produce an output voltage that can be higher (like a boost power stage) or lower (like a buck power stage) in magnitude than the input voltage with an output voltage that is opposite in polarity from the input voltage. For example, a positive-to-negative buck-boost converter can convert 5 volts to 12 volts (step-up) or 12 volts to 5 volts (step-down).

To maximize the utility of the solar cell (monocrystalline solar cells) panels, this study will incorporate a maximum power point tracking (MPPT) device and battery technology into the solar power management system (SPMS) as shown in **Figure 6**. Hence, the approach of this study is to optimize SPMS, power conversion, and battery management systems.



(a) (b)

Figure 6 : Solar power (a) configurations of SPMS, (b) equivalent circuit (Shiau et al., 2009)

The complete engineering drawing of the integrated structural supports, power mechanisms, power circuitry, and ICU monitor are shown in **Figure 7**.

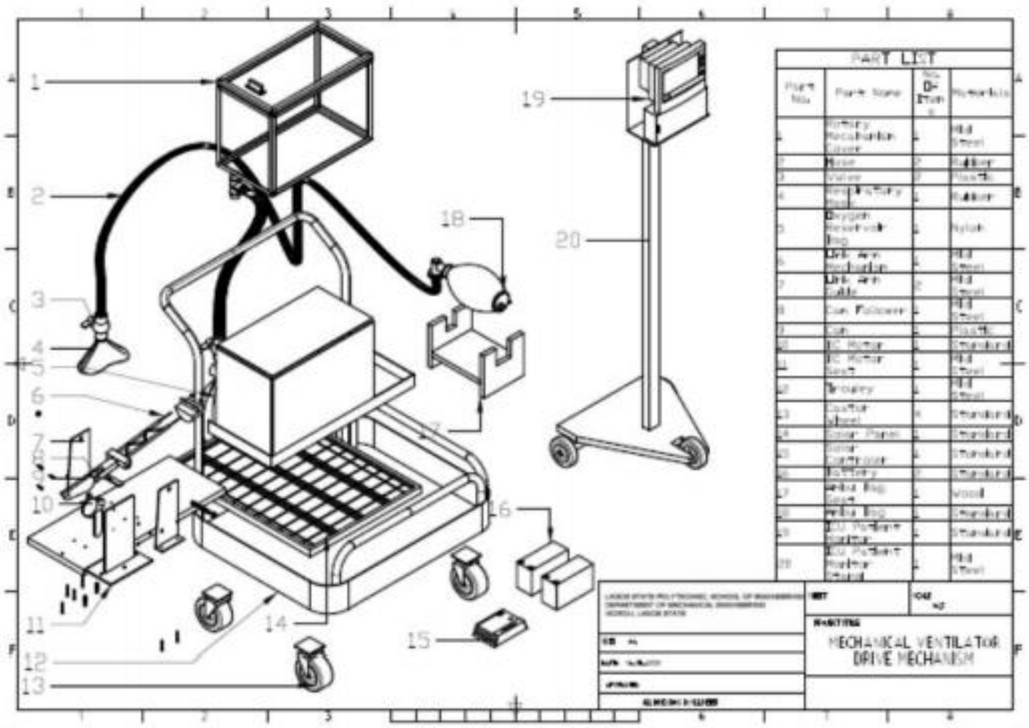


Figure 7 : Assembly drawing of the entire mechanical ventilator

2.5 Performance evaluation

The performances of the mechanical ventilator for each concentric cylindrical ring effect on the BVM bag both adults and children are displayed on an LCD screen to yield tidal volume delivery, respiratory rates, and I/E ratio. Data analyses of graphs are shown as mean ± standard deviation. Testing of bags and motors were continuously operated for 8 hrs. per day for about five days. The motor temperature and switching from AC/DC adapter to solar power source were monitored. In addition, the period the solar power source was used up was also noted.

3. Results and discussion

3.1 Oscillating cam/roller follower curve

The result of the oscillating cam/follower lifts is shown in **Figure 8**. The result indicated that the follower rises along with the cam within a 38º angle. However, there was a sudden fall of the follower due to the self-inflation effect of the BVM bag.

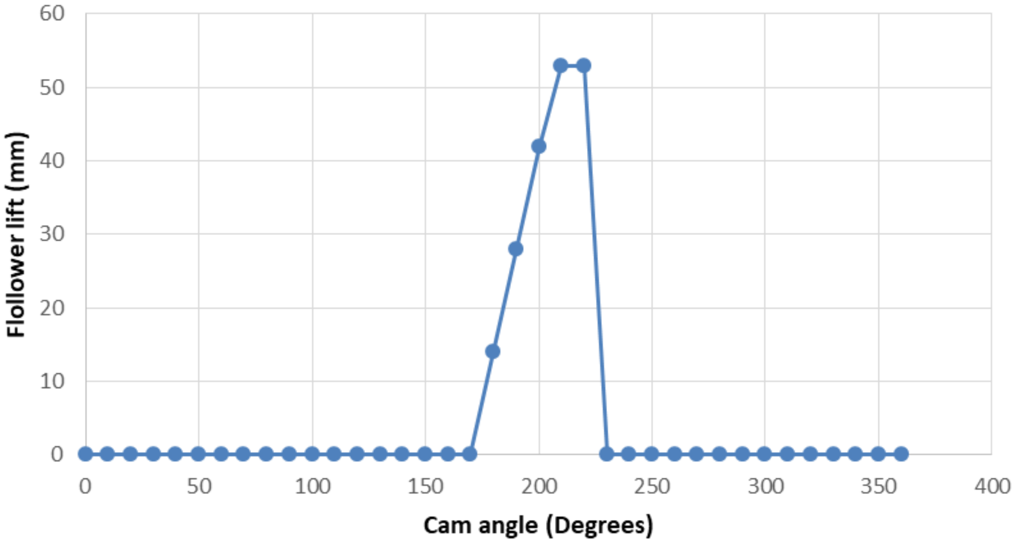


Figure 8 : Profile of oscillating cam and roller lifts

3.2 Development and fabrication

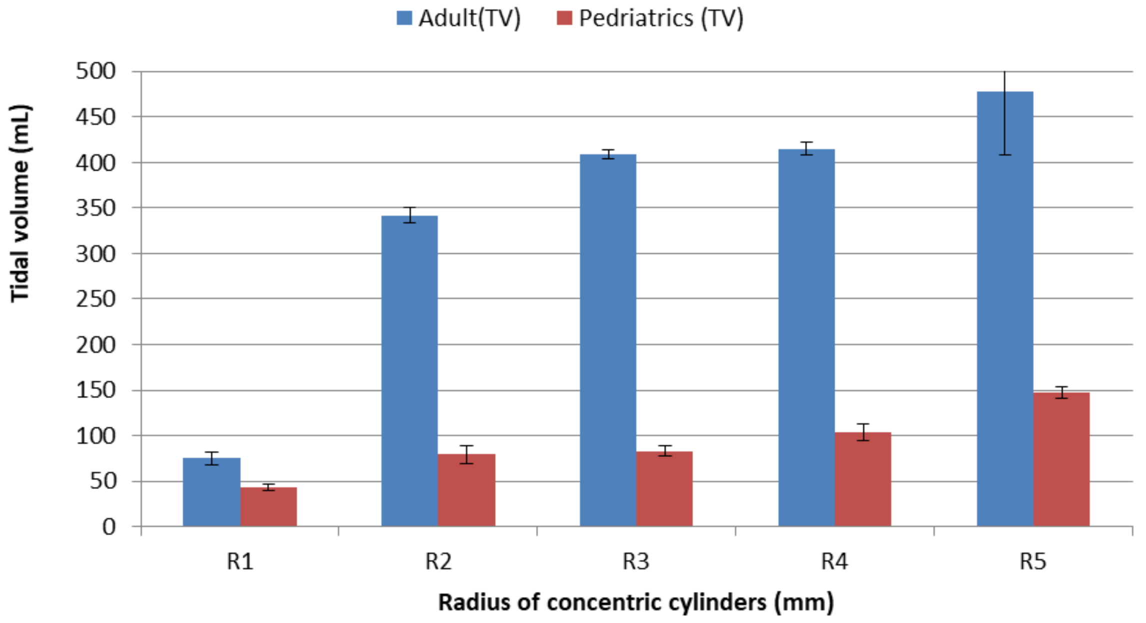
The complete fabrication of the mechanical ventilator, supports, mechanisms, power system circuitry, monitors, etc. are shown in **Figure 9.**

Figure 9 : Completed mechanical ventilator unit with a monitor and solar panels

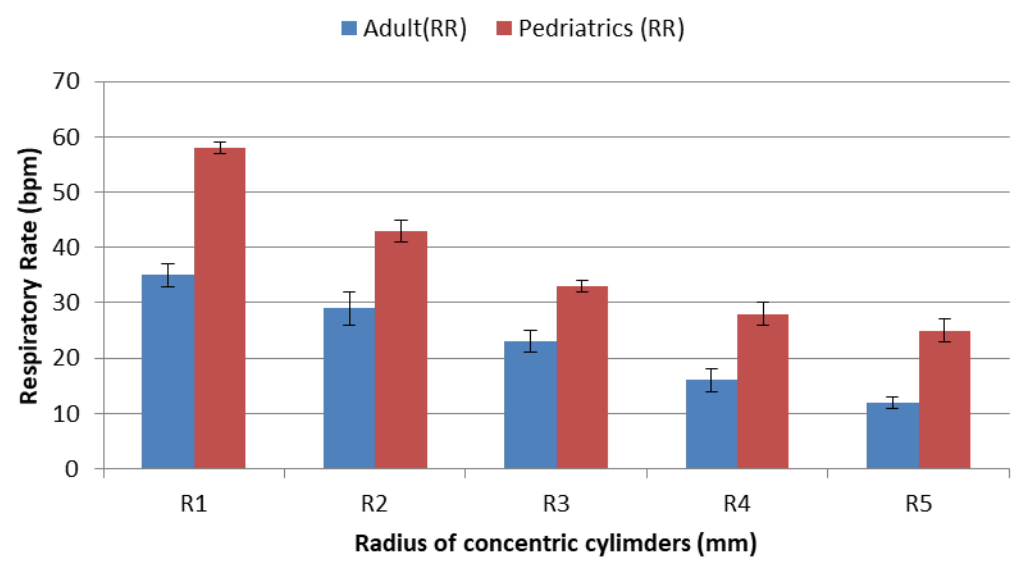
3.3 Tidal volume (Vt) and respiratory rate (RR) assessment

The result of the tidal volume and respiratory rates measured from the respiratory function monitor at the expiratory valve using an assist-control (AC) mode is shown in

Figure 10 (a) and (b) respectively. The results indicated that tidal volume increases with the sizes of the concentric rings for both adults and children. For adults, Vt varies from 75 to 478 mL, and for children was between 43 and 147 mL. This result of maximum and minimum mean tidal volumes of air was similar to that obtained in the literature of similar studies by (Al Husseini et al., 2010; Hossain, Halder, Al Aman, Islam, & Rahman, 2018; Khoury et al., 2016). Hence, the varying tidal volumes provide a means of adjustments of tidal volumes to the weight of the patient.



(a)



(b)

Figure 10 Results obtained from the ICU monitor; (a) tidal volume, and (b) respiratory rates

The maximum and minimum respiratory rates for adults and children decreases with increasing sizes of the concentric rings as shown in

Figure 10 (b) with respective values for adults from 35 to 12 bpm and children from 58 to 25 bpm that was similar to results from (Khoury et al., 2016). This indicated that designs from this study of concentric rings to alter the respiratory rates gave a significant decrease in BVM for children than for adults. However, this can greatly be affected by adverse conditions such as COVID-19, asthma, anxiety, pneumonia, congestive heart failure, lung disease, use of narcotics or drug overdose, etc. In addition, the respiratory rate is also controlled by a 48 rpm motor operated at full power. The measured I/E ratio (I:E ratio), or inspiratory expiratory ratio measured on the respiratory function monitor ranges from 1:2, 1:2.1, 1:2.3, 1:2.4, 0.7:2.1. At rest, it is usually about 1:2. This means that exhaling is slower than inhaling.

The running of the mechanical ventilator for 8 hrs, every day for 5 days did not produce any sudden increase in the temperature of the electric motor and switching from one power mode to another was seamless. However, the period of power supply from the solar power source did not go beyond 5±0.15 hr duration. In addition, testing of the mechanical ventilator resulted in chattering noise during the first contact between the cam and follower despite the use of softer cam material (Perspex).

4.0 Discussion

The shortage of mechanical ventilators due to COVID-19 pandemic has led to the development and testing of this mechanical ventilator in an attempt to simulate hand-operated BVM bags into automated bag-compression devices for healthcare providers with limited respiratory care expertise. The materials for this prototype have utilized about 75% local material. Further reduction is possible in future work. However, the chattering noise can be very difficult for some patients to bear. Future work of this proof-of concept prototype can consider noise reduction if the roller follower is made to always be in contact with the cam. The clinical trials of this prototype are necessary on artificial lungs and real patients. It is expected that further refinement of this prototype is necessary for local production and utilization to militate against the ravaging effects of various COVID-19 strains or variants.

The durability of the designed and fabricated mechanical ventilator may be limited by the lifespan of the electric motor and BVM bag with no capacity for automated augmentation or leak compensation, unlike fully functional ICU ventilators.

To prevent the mechanical ventilator from delivering air at excessive pressure to the patient, a pressure relief valve is not only necessary, but it must also limit the peak inspiratory pressure (PIP) from the BVM to 20–25 cmH_2O for children and 45 cmH_2O for adults (Organization, 2016); as it can lead to lung damage during resuscitation,

4. Conclusion

The study proves the concept of automating the BVM for developing a low-cost portable mechanical ventilator. Improvements to the model will lead to a successful and useable portable mechanical ventilator for actual emergency cases where existing sophisticated devices are not present. Although the device cannot perform like existing devices, its low cost justifies its use in emergency cases. Future development scopes will consider more electronic control features for various ventilation parameters like tidal volume; inspiration to exhalation time ratio etc. This study has provided a low-cost solution to ventilator shortages using local means of providing short-term oxygenation and ventilation emergency resuscitator supports for COVID-19 patients and other respiratory ailments provide. Clinical trials are necessary to establish safety and efficiency before use on patients with various breathing problems.

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