Development and Performance Evaluation of a Foot-Operated Fluid Aspirator

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ORIGINAL RESEARCH

Abstract— Fluid aspiration is a common procedure undertaken during emergency situations in hospitals to remove airway blockages in patients. This activity is capable of increasing the risk of transmission of infections from patients to physicians or vice versa. Prevention or significant reduction of such infections is necessary. The goal of this paper is to develop and evaluate a foot activated fluid aspirator. The proposed device was designed using Autodesk Inventor Software. The device was designed and fabricated largely from locally available materials including plane sheets of metal, bacteria filter, two canister (waste bottle), 3 meter length tubing, pressure regulator control knob, AC power switch, 2 horse power compressor motors, 220V contactor relay switch, air flow adaptor, four pieces of castor (rollers), four cans of spray paint (white and black), one full length plywood (Formica), two yards of furniture mat, pressure gauge, Light Emitting Diodes (red and orange), canister hanger, window net (hard),13 amps AC plug, 10 µf AC capacitor, and one diathermy pedal switch. The fluid aspirator is dual powered and activated using a one-way switch and a single mechanical pedal switch. Evaluation of the device functionality returned a suction time of 2.02 ± 0.23 s compared to a suction time of 2.21 ± 0.22 s obtained from a functional standard commercially available fluid aspirator and with a p-value of 0.3429 indicating no statistically significant difference between the two suction times. The results demonstrated the effectiveness of the device in absorbing both fluids at specific pressures. Therefore, the device could be immensely beneficial for use in hospitals.

Keywords— fluid aspirator, fluid extraction, pedal switch, suction machine.

1 INTRODUCTION

Fluid aspirators also known as medical suction machines are very essential class II medical devices used in clinical practice to remove undesirable liquid inside the body such as mucus, blood and other biomaterials that cause obstruction in the human body. Consequently, physicians can have a clearer view of organs previously blocked by unwanted blockages (Lorenzo et al., 2017). In addition, this device presents other immense benefits in clinical practice especially as it is known to reduce the risk of complications that may occur due to accidental puncture of internal organs. Medical suction is used for a wide variety of patients both young and old to clear the airway, empty the stomach, decompress the chest, and keep the operative field clear (Wilson et al., 2005). It is an invaluable medical equipment used in various medical specialties especially surgery, anaesthetic resuscitation and intensive care. Recently, the use of fluid aspirators in clinical practice has significantly increased in scope. In most clinical departments, they have become necessary for both diagnostic and therapeutic interventions.

Some of the important therapeutic use of fluid aspirators include the clearing of respiratory airway and depletion of liquids during medical procedure (Blackbourne, et al. 2012; Peri et al., 2022). Despite its numerous benefits, the use of fluid aspirators could lead to suction-induced trauma (Kumar et al., 2015). In addition to this, improper usage of fluid aspirators could most likely cause bleeding, infections, cardiac arrests and death in patients (*Day et al., 2002)*. The use of suction machines has been linked to surgical site infections (*Mohammed, et al., 2012)*. Therefore, it is imperative not only to ensure that the device is designed according to standards but also that users receive adequate training (Pillay & Pillay 2009) [8]. The well-known ISO 10079 series provide standards for medical suction machines. A fluid aspirator comprises an inlet and an outlet (Morrow et al., 2004). The device uses compressors to create vacuum with pressure of between 0 and 600 mmHg, flow rate of 30 litres per minute (LPM). There are a wide variety of aspirators in the open market designed mostly in highly developed countries without much consideration to the peculiarities of low- and middle-income countries. There are 3 major types of suction machines. They include suction of the pipeline, mobile suction, and low suction (Senavongse, & Sutdaen 2012). Reliability is an important consideration in the choice of fluid aspirators. The device should be able to do suctioning at prescribed pressure with minimal downtime.

In recent times, a number of fluid aspirators have been proposed to support various medical procedures. Taylor (2006) developed a medical suction machine to support

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rural clinics in Malawi. Shannon and Goldsmith (2009) described in details the functions and features of suction machines. They however did not develop a medical suction device. Kennedy and Herod (2015) described suction devices. While stating the advantages, the authors also stated the adverse effects of suction devices soft tissue trauma. Grunert et al., (2018) developed an adaptable suction machine that can be used for patients with different body anatomy. The device was evaluated on different human cadavers' skulls by experienced surgeons who found it suitable. However, they did not consider possible transmission of infection from the patients or cadavers to the physicians. Zhang, et al., (2021), proposed an ultrasonic aspirator consisting of a Langevin transducer was developed for cartilage removal. Peri et al., (2022) did a review of current standards for suction machines and recommended some changes. They identified the need important manufacturing and clinical standards such as ISO 10079. The limitation of most conventional fluid aspirators proposed in previous studies is the problem of cross contamination. This leads to the transmission of infection from patients to healthcare workers or vice versa.

The paper aims to present the development and evaluation of a patient friendly foot activated medical fluid aspirator suitable for Low- and Middle-Income Countries especially with the prevailing conditions caused by Corona Virus Disease (COVID-19) pandemic and other infectious diseases. The device was designed based on the need to minimise direct contact between patients and health workers in order to reduce disease transmission. This is the main advantage over conventional fluid aspirators. Furthermore, there is a huge shortage of medical suction machines in Nigeria as the country relies heavily on the importation of the device. A study conducted in Cross River State, Nigeria identified a huge shortage of medical suction machines in hospitals. It was reported that over 70% of the hospitals had no functional medical suction machines (Kalu et al., 2022). Given the utility of the device in healthcare, there is need for further innovations in the design of medical fluid aspirators.

2 METHODOLOGY

2.1 THEORETICAL FRAMEWORK

In conventional medical fluid aspirators, a flow is created by reducing the pressure at one end of the tube. This reduction in pressure produces a negative pressure which overcomes a resistance and induces a flow. The relationship between flow, pressure and viscosity of fluid is depicted by Hagen–Poiseuille equation. It states that "the flow rate, Q is directly proportional to the pressure difference between the ends of the tube and the fourth power of the radius but inversely proportional to the length of the tubing, L and the dynamic viscosity of the fluid, μ "(Vandenberg et al., 1999; Ostadfar et al., 2016).)

$$\Delta P = \frac{8\mu LQ}{\pi r^4} \quad (1)$$

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Where ΔP is pressure change, L is the length of tubing, μ is the dynamic velocity.

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Importantly, pressure driven systems and changes in the speed of the fluid can be used to improve fluid pressure. Pressure is usually calculated as force divided by the area. The area of the container of the fluid determines the pressure required by the aspirator to lift or draw the volume of fluid from the patient. According to Bernoulli's principle, a rise in the speed of a fluid which takes place concurrently with a drop in static pressure (Batchelor 2000). This implies that there is no friction in an ideal fluid. Bernoulli's equations are generally useful in the estimation of the pressure at any point in a fluid. In fluids, viscosity is caused by frictional forces between particles within a fluid creating some resistance in the shearing motion of the fluid (Jiang et al., 2011). Accordingly, viscosity can be mathematically defined as shearing stress ($\frac{F}{A}$) divided by velocity gradient ($\frac{\Delta v_x}{\Delta Z}$ or $\frac{dv_x}{dZ}$) in a fluid.

$$\eta = \frac{\frac{F}{A}}{\frac{dv_x}{dZ}} = \frac{FdZ}{Adv_x} \quad (2)$$

The relationship between the resulting shear of a fluid, the force applied (F) and its viscosity (η) is clearly indicated in equations (7) and (8) which is similar to Newton's second law of motion ($F = ma$).

$$\frac{F}{A} = \eta \frac{\Delta v_x}{\Delta Z} \quad (3)$$

$$F = m\frac{\Delta V}{\Delta t} \quad (4)$$

2.2 MATERIALS

The device was designed and fabricated largely from locally available materials in compliance with the local content policy. This study utilizes local materials in the design of the fluid aspirator with a view to reducing cost and increasing the potential for local manufacturing. The use of local raw materials in the fabrication of the device has potential economic benefits to the local economy. In developing the foot activated medical aspirator, the following materials were used: plane sheet of metal, bacteria filter, two canister (waste bottle), 3 meter length tubing, pressure regulator control knob, AC power

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switch, 2 inches nails, 2 horse power compressor motor, 220V contactor relay switch, air flow adaptor, four pieces of castor (rollers), four cans of spray paint (white and black), one full length plywood (Formica), two yards of furniture mat, pressure gauge, Light Emitting Diodes (red and orange), canister hanger, window net (hard),13 amps AC plug, 10 μf AC capacitor, one diathermy pedal switch, and two dozens of furniture screws. Figure 1 shows the top cover of the aspirator during fabrication. Figure 2 shows the top cover of the aspirator casing after fabrication.

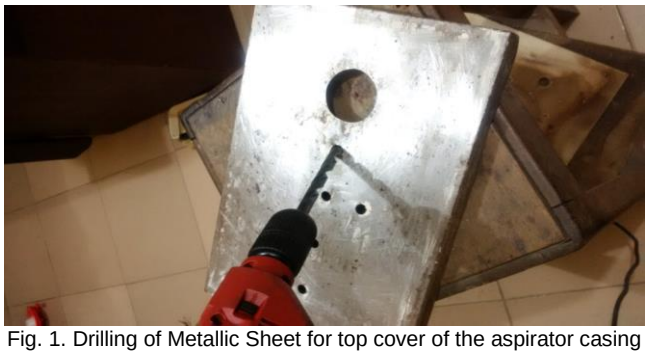

Fig. 1. Drilling of Metallic Sheet for top cover of the aspirator casing

Fig. 2: Top cover of the aspirator casing after finishing

Table 1. Material Selection

S/N	Part	Material	Reason for material selection
1	Base and cover for Casing	Aluminium sheet with top coated with Formica	High tensile strength
2	Patient tubing	Rubber material	Biocompatible and non-toxic material.
3	Pedal switch	Plastic	High insulation and protection from electric current
4.	Sealed canisters	Bottles	Prevent spillage of waste fluids and spread of infection

The design requirements for the medical suction machine relative to ISO 10079 series is shown in Table 2.

Table 2: Design Requirements

S/N	Design characteristics	Description
1	Power source	The device should be powered by AC source that is able to drive the pump
2	Power Switch	Pedal switch required to enable foot activation
3	Biocompatibility	Parts that make direct contact with the user or patient should be made of biocompatible or non-toxic materials
4	Safety	Electrical safety requirement of the aspirator in terms of not exposing the user or patient to electric shock. Mechanical safety requirements ensure the users and patients are protected from mechanical hazards.
5	Pressure range	The design is required to have an adjustable vacuum pressure range of 0 – 550 mmHg. It should serve neonates (60 – 100 mmHg), toddlers (80 -120 mmHg) and adults (100 mmHg – 200 mmHg).
6.	Flow rate	The device should have an adjustable maximum flow rate of ≥ 20 Litres per minute (lpm).
7	Target users	Adults and paediatrics are the target users of the device.

2.3 Device Description

Figure 3 shows the Computer Aided Design (CAD) of the fluid aspirator with the dimensions clearly indicated. The CAD design in Figure 4 shows the top view of the fluid aspirator. The CAD design in Figure 5 shows the waste bottle with dimensions clearly indicated. The block diagram of the foot activated fluid aspirator is shown in Figure 6.

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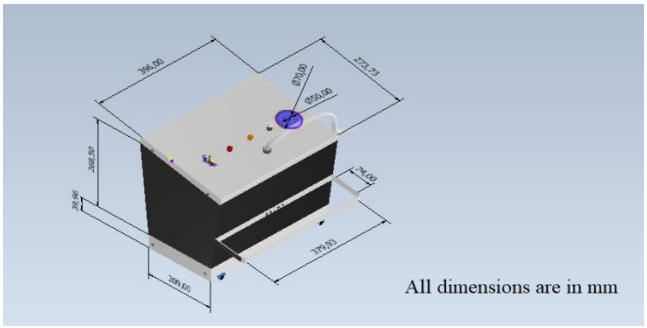

Fig. 3. Computer Aided Design of the Medical Aspirator

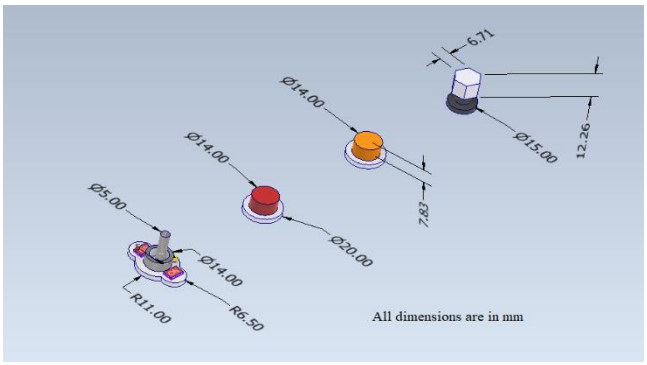

Fig. 4. CAD design of Top view of the Fluid Aspirator

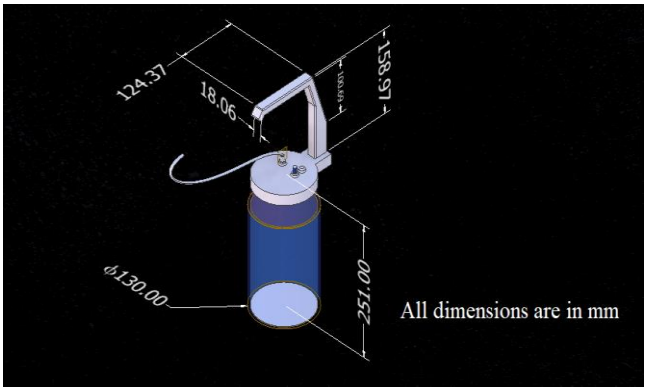

Fig. 5. CAD Design of Waste Bottle of the Fluid Aspirator

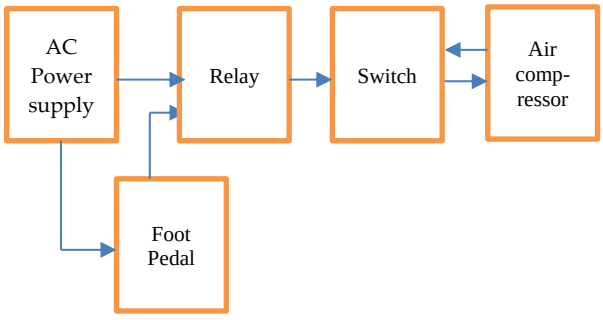

Fig. 6. Block Diagram of the Foot-activated Aspirator

The device was fabricated with various materials locally sourced from two markets in Lagos, Nigeria. It includes a wooden board (Formica) covered with furniture tangle for easy cleaning and removal of stains on the surface. Metallic sheet and plastic are the most utilized materials for the lodging of a liquid suction apparatus. However, they have a tendency to retain any liquid spilled on them in spite of cleaning. Also, the device is made of a mechanical framework that includes the metallic base (bottom), where the negative air blower and other electrical parts will be mounted; the metallic (top) where the markers, weight controller, weight check, mechanical switch and T-connector will be mounted. The metallic sheet was shaped to the required size followed by the drilling of holes/ports to ensure the mounting of mechanical switch, indicators, pressure regulator and the pressure gauge. The neutral line of the AC supply is connected to line 2 of the relay and subsequently connected to the line 2 of the air compressor. The operation of the single gate switch (SW) is independent of the relay and foot pedal; it can power the air compressor directly with the AC signal received from the power supply outlet. The air compressor operates in dual mode. It can be powered by the foot pedal as well as the single gate switch (SW). The device is powered by a 240 AC supply. When the equipment is plugged to the AC mains, it was observed that current flows through the AC cord directly to one line of the foot pedal and line 1 of the terminals of the relay. It also includes a compressor that generates negative pressure that enables it to suck in fluid from the outer chamber. The plane sheet of metal was cut into two and shaped to the desired measurement. A drilling machine was used to create a port for the installation of the pressure gauge, indicators, pressure control knob and power switch. The two indicators (red and orange) are to indicate the power and operation mode of the fluid aspirator. A foot pedal switch designed from electrosurgical unit was reconfigured to work as a single gate switch for the sake of this fabrication. The diathermy pedal switch is connected in series with the contactor relay switch which energizes the compressor motor when the pedal switch is activated. The castors (roller) will ensure easy movement of the fluid aspirator from one place to another.

When the foot pedal is activated, it energizes the 2-way mechanical relay that turns ON the Air Compressor. The air compressor generates a negative air –pressure from the surrounding that passes through the fluid collector bottles. The fluid (unwanted waste) which is denser than air is trapped in the bottles that would be disposed when the surgical procedure is over. The negative air pressure keeps on moving through a bacterial filter that channels and traps any particles or microorganisms at that point tends to stream into the air compressor. The bacteria filter is vital as it reduces the risk of infection. The weight control handle is utilized to direct the negative pressure or set the craving weight required by the end client. The negative pressure gauge rises at whatever point the patient suctioning test or tubing detected any impediments or blockages. Stream rate refers to the rate of expulsion of air, liquid, or emissions from the patient.

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Under ideal conditions, clinicians require the best stream rate out of a vacuum framework at the most reduced negative weight. The stream rate is determined by:

- The measure of negative weight (vacuum)
- The obstruction of the suction framework
- The thickness of the issue being expelled

The negative weight utilized sets up the weight angle that will move air, liquid, or emissions. Material will move from a region of higher weight in the patient to a zone of lower weight in the suction contraption. The opposition of the framework is resolved principally by the thinnest piece of the framework commonly, a tubing connector however the length of tubing in the framework can expand obstruction also. Watery liquids, for example, blood will travel through the suction framework considerably more rapidly than will thick substances, for example, sputum.

2.4 DEVICE EVALUATION

To determine the functionality and efficacy of the device, It was initially tested by using it to extract water in a cylinder while the device was powered by placing the foot on the switch. The device functionality was further tested by comparing the suction time and flow rate for the aspiration of 100 ml blood in the developed device with a standard commercially available fluid aspirator.

3 RESULTS AND DISCUSSION

The fluid aspirator developed in this study met all the design requirements stated in Table 2. It consists of a 230 V AC power source, a pedal switch used to activate the aspirator, and a non-toxic material for fluid extraction. The device was validated by testing the flow rate of 100 ml of blood on the developed foot activated fluid aspirator and commercially available standard fluid aspirator.

Fig. 8. Foot Activated Fluid Aspirator

The results are shown in Table 2. The mean time in seconds for the aspiration of 10 ml blood with our developed fluid aspirator was 2.0375 seconds. While the mean time for the extraction of blood from the standard fluid aspirator was 2.21 seconds.

Table 3: Results of Fluid Aspiration

	Suction Time (s)		Flow Rate (ml/s)	
Blood Volume (ml)	Developed Foot Activated Aspirator	Standard Fluid Aspirator	Developed Foot Activated Aspirator	Standard Fluid Aspirator
100	1.83	1.99	54.64	50.25
100	1.86	2.05	53.76	48.78
100	2.18	2.37	45.87	42.19
100	2.28	2.43	43.86	41.15

Table 4: Data Analysis

Parameter	Suction Time (seconds)	
	Developed Foot Activated Aspirator	Standard Fluid Aspirator
Median	2.02	2.21
Standard Deviation	0.23	0.22
P-Value	0.349	

The median ± standard deviation time for aspiration of 100 ml of blood in the developed and standard devices were 2.02 ± 0.23 and 2.21 ± 0.22 seconds respectively. The Mann-Whitney U test was performed to determine if there is a significant difference between the suction time in our developed device and the standard device. A *p-value* of 0.3429 was obtained at 95% confidence level. The result confirmed that there is no statistically significant difference between the performance of our developed device and the standard device. The functionality of different types of medical suction machines is assessed by the maximum displacement and level of sub-atmospheric pressure produced by the device (Shannon & Goldsmith 2009). However, temperature determines the viscosity of fluid; the lesser the temperature the higher the viscosity (Holmes et al., 2010). Figure 7 shows the fabricated foot activated medical aspirator. It includes the pedal switch which was included to prevent cross contamination between patients and clinicians as the use of foot to activate the fluid aspirator minimizes the exposure of the hands of the clinician to infection. However, the furniture mat proved to be a good a material in fabricating fluid aspirator using wooden plank; however, Medicinal suction and the administration of gathered liquids are fundamental.

This study proved that manufacturers of fluid aspirators often ignored the facts that the materials used in fabricating the housing of fluid aspirators should have been discontinued long ago; mostly the ones shipped to Nigeria for sales. This poses a lot of risks to patients and

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health assistants; because the non-repellent materials used in the fabrication of the housing of some fluid aspirators are easily contaminated and unable to prevent the spread of viruses. It is imperative for safety considerations to influence the choice of the foot activator material. Metallic materials are largely unsafe and do not provide the required insulation from electric shock.

4 CONCLUSIONS

In this study, a foot activated fluid aspirator was designed and fabricated capable of minimizing the transmission of infections. The device was fabricated using locally available materials comprising wooden board (Formica), Metallic sheet and plastic materials carefully prepared to meet design requirements. The device also includes a foot activator, which is used to power the fluid aspirator. Thus, reducing infections transmitted by hand posed by the transmission of infectious diseases during fluid aspiration such as COVID-19, Lassa fever and Ebola from patients to physicians or vice versa. Therefore, the developed fluid aspirator is an invaluable medical device that will be immensely beneficial to hospitals and clinics in Nigeria and other developing countries for diagnostic and therapeutic purposes.

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