Preliminary Implementation of the Next Generation Cannulation Simulator

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Abstract*—Extracorporeal Membrane Oxygenation (ECMO) is a highly complex/critical lifesaving procedure known to support patients with cardiac and respiratory issues. Patients on ECMO are monitored 24/7 by a team of highly trained ECMO team comprising nurses, physicians, respiratory therapists, and perfusionists promptly intervening to any potential emergency situation. Simulation-Based Training (SBT) allows clinicians to experience and practice realistic hands-on procedures and scenarios without any risk. In ECMO, cannulation is a critical procedure performed to externally reroute the blood flow so it can be re-oxygenated by the ECMO machine before being recirculated through the patient's body. In a close collaboration with Hamad Medical Corporation (HMC), this project aims to develop a cost effective, realistic, and user-friendly ECMO simulator focusing on the venous and arterial cannulation procedure, The main features of this simulator include cannulation emergencies caused by low pressure flow, excessive force, recirculation, or mispositioned wire/cannula. Therefore, the ECMO cannulation simulator will not only greatly contribute to the initial and ongoing local training of HMC ECMO clinicians but also contribute to improving patient care by lowering the risks associated with the cannulation process.

***Keywords*—ECMO, Cannulation, SBT, Embedded systems**

I. Introduction

Extracorporeal membrane oxygenation (ECMO) is a complex rescue therapy that caters to patients with relatively short-term respiratory and/or circulatory complications [1]. Since the invention of ECMO, it has benefitted around 53,000 patients from around the globe with fatal diseases, with a survival rate of 75% for patients that started with 25% survival rate before ECMO [2]. Although ECMO has gained in popularity and survival rates are increasing, it is still associated with multiple mechanical complications and procedural emergencies which require the rapid intervention of a well-trained multi-disciplinary team of ECMO clinicians to ensure the survival of the patients [3].

Simulation-Based Training (SBT) is evolving in terms of the technology and educational approaches used to include new clinical procedures, with interactive patient simulators that breath, have a heartbeat, and can bleed among other functionalities [4], [5]. SBT is becoming a gold standard for training healthcare professionals, especially in critical care as in ECMO, as it provides a safe immersive environment for trainees to understand the ECMO-patient interactions and how to operate effectively as a team [6]–[8].

Hamad medical corporation (HMC) has been treating ECMO patients since 2013 and initially relied on sending a team of clinicians overseas to undergo an extensive training program. As the need for ECMO is growing, the need for more ECMO trained clinicians also increases. The ability to locally train ECMO clinicians has therefore become a requirement in order to sustain the development of this service.

The main goal of this joint venture between Qatar University and HMC is to develop a cost efficient, realistic, and educationally effective ECMO simulation training platform. The remaining sections of this paper cover the literature review describing the cannulation process and explaining the main features needed of an ECMO simulator. A brief discussion of existing simulators is presented in section II. Section III then discusses our proposed design and its main features while Section IV explores the proposed system implementation and results. Section V concludes the paper.

II. Literature Review

ECMO SBT is essential for the sustainable development of any ECMO department though it is costly, as most available cannulation simulators are expensive, non-user friendly, and overall miss important features that contribute to the cannulation experience. Most cannulation simulators comprise only one loop with a laminar flow and generally lack realism as described in Table I. In addition, most simulators are quite expensive in relation to what they can do. Even the newest and the most advanced cannulation simulators which can cost around 20k USD do not address the anatomic realism aspects presented in Fig. 1[9]. Based on the identified limitations of the current simulators, the HMC team started to work on a new design to provide a better training experience and initiated the collaboration with an engineering team from Qatar University [10].

TABLE I. EXISTING SIMULATORS SUMMARY

Existing Cannulation Simulators	Metric				
	Realism	**Performance**	**Features**	**Drawbacks**	**Ease of use**
This work	High	High	• Easy maintenance • Realistic dual flow • Smart interactive learning experience • Relatively cheap • Anatomical realism	• Recalibration of sensors	Easy to use
Chan *et al.* [9]	Average	High	• Easy maintenance • ECG simulation • Has both arteries and veins with pulsatile flow	• Expensive • Limited anatomical realism • Includes adult model only	Easy to use
Allan *et al.* [11]	High	High	• Realistic cases (oozing, bleeding) • Realistic • Blood flow • The mannequin has tissue	• Expensive • Includes infant model only • Simulation of veins only (single blood flow loop)	Complicated interface
Thompson *et al.* [12]	Average	Low	• Low cost • Realistic shape	• Simulation of veins only • Poor blood flow simulation (single blood flow loop)	Easy to use and assemble
Endo *et al.* [13]	Average	High	• Low cost • Realistic appearance	• Blood flow Simulation • Simulation of veins only (single blood flow loop)	Easy to use

III. PROPOSED DESIGN DESCRIPTION AND ANALYSIS

Cannulation for ECMO is the act of passing a cannula into the circulatory system from an access point, usually either in the femoral or jugular region, towards the heart in the inferior vena cava (IVC) parallel to the hepatic vein in veins, and the distal aorta in arteries [14]. Cannulation is essential for ECMO as it bridges the ECMO machine to the human body.

The four essential tools of ECMO cannulation are:

- The needle which is used to pierce the flesh.
- The guidewire, which is used to guide the wire through the blood vessel;
- The dilators of different sizes to dilate the skin to the size of the cannula
- The cannula (sometimes two or even three are used) that is used to reroute the blood into the machine and back to the patient.

There are four main steps to perform the cannulation. The first step is the insertion of the needle into the flesh and into the appropriate blood vessel. The challenge in this step is to insert the needle into the veins since it is situated below the arteries. The second step is to introduce the guidewire into the needle to the desired blood vessel. For arteries, the position to reach is the distal aorta where the two femoral arteries meet and for veins it is the end of the IVC right before the heart beside the hepatic vein. The main challenge in this stage is that the guidewire could end up going through the wrong track and cause damage, which could result in internal bleeding. The next step is to pull the needle out of the guidewire while keeping pressure on the access point with a finger to reduce the bleeding to a minimal amount. The last step is to insert the cannula into the guidewire up to the desired position.

The proposed design consists of two subsystems: (a) ECMO machine simulator and (b) cannulation simulator. The first subsystem is very innovative as it concentrates on simulating the ECMO machine itself using a modular design where the instructor has the control to simulate different complications. The main innovation of the simulator is the use of thermochromic ink as a substitute for animal blood which makes its maintenance cheaper while upholding high standards for realism in terms of oxygenation and deoxygenation color change [15]–[23].

The second subsystem, which is the focus of this paper, is the cannulation simulator which is mostly concerned with emulating the human circulatory system in the context of training for ECMO cannulation. The design of the cannulation simulator was done by a multidisciplinary team of engineering students with close collaboration with HMC ECMO clinicians and a simulation education specialist in order to ensure a high level of realism, where it is necessary for educational requirements [24]. Fig. 1 represents the proposed solution diagram in which the red represents arteries and the blue represents veins. The components needed are tanks, pumps, a microcontroller, force sensing resistors, flow meters, tubing, the patient's body, and the silicone rubber and the molds to make the cannulation pads. The main features of the simulator could be categorized as closed circulatory loop, the cannulation access points, and the ability to make involuntary procedural errors to experience the resulting emergencies.

A. *The Closed loop*

The main new features of the closed loop, as seen in Fig. 1, are the interconnected vein and artery loops, the incorrect paths, and the cannulation stopping points in the heart region. Like in a real person, the arterial flow is pulsatile and the venous flow is laminar. The interconnected loops are essential for the accurate emulation of cannulation as it mimics a real-life human circulatory system, however the incorrect paths in the system are added in order to emulate the challenges of cannulations. For this an extension is added to the venous loop in order to emulate the renal vein which is a common incorrect path the guidewire takes. Cannulation stopping points are also emulated by having a chest pad over the heart that is ultrasoundable in order to determine the correct positioning of the venous cannula at the end of the IVC and parallel to the hepatic vein. In addition, the arterial closed loop has a pulsatile flow that helps distinguishing them from the veins with their laminar flow.

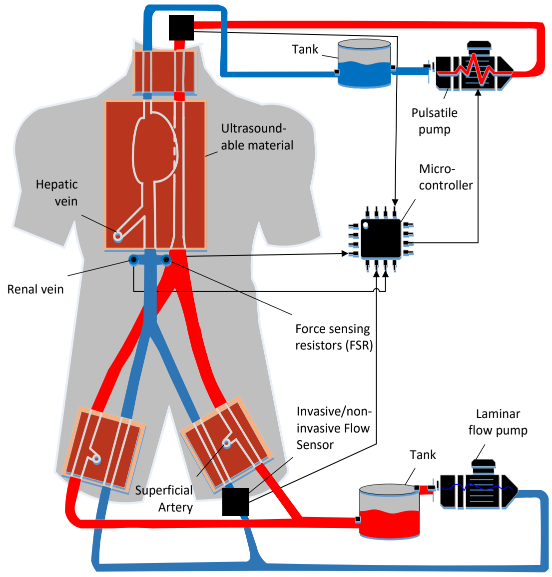


Fig.1 Block diagram of the proposed cannulation simulator

B. Cannulation Access points

Cannulation access points are also an important part of the simulation as it is the element that helps the trainee contextualize the feeling of cannulation.

In order to accurately emulate the human body, an ultrasound scan of the femoral cannulation access point was used as a reference for the cannulation access pad that the team designed.

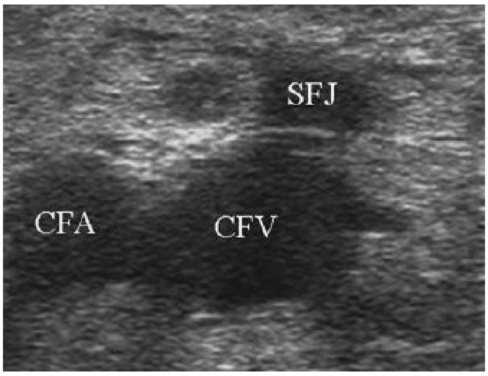


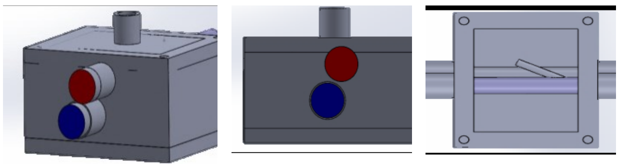
Fig. 2 Ultrasound of common femoral artery(CFA) and common femoral vein(CFV) [25]

The main features as seen in Fig. 1 that need to be incorporated into a cannulation simulator are the following:

- The femoral artery has a diameter smaller than the femoral vein.
- The femoral artery is on top of the femoral vein.
- There should be a superficial artery to emulate wrong paths for the guidewire.

There are features that cannot be seen in an ultrasound image such as the pulsing of the common femoral arteries which could be seen in the ultrasound imaging video of the femoral access point [26]. Moreover, the flow should be pulsatile in the arteries and laminar in the veins.

The main features of the cannulation access points inspired from Fig. 2 are their ultrasoundability, offering the possibility of incorrect paths, the palpable pulse in the artery, and the anatomical correctness of the cannulation pads. Firstly, ultrasound-ability is one of the most fundamental features since it is usually used to correctly introduce the guidewire. Secondly, the cannulation pads are designed to include the superficial artery in order to emulate the wrong path the guidewire could go through in the process of cannulation. In addition to that, the pad will have a pulsing mechanism to make the arteries evident, as it is also by touch that the clinician can identify the arteries from the veins near the access point. Lastly, the pads are designed in a way that mirrors the human cannulation access points, as the veins are bigger in size than the arteries. To make the reproduction of the pads easier, a mold was designed in order to make the process simple by pouring the liquid silicone rubber in the mold and leaving it to solidify. The mold design is shown in Fig. 3.



(a) (b) (c)

Fig. 3 Cannulation pad mold design viewed from different angles.

C. Procedural emergencies

To make the educational process more interactive, sensors for procedural emergencies were introduced as they are meant to alarm the instructor if a trainee causes a procedural emergency. The main procedural emergencies incorporated into the simulator are bleeding and guidewire insertion in the renal vein. Firstly, the bleeding emergency is based on the idea that in a closed loop if there is a drop-in flow then the cause is due to some form of hemorrhage and therefore the system will detect it and alarm the instructor. In addition, a sensor has been placed in the simulated renal vein because a common clinical error that occurs is that the guidewire gets pushed into the renal vein, which can cause fatal internal bleeding. The solution to detect this issue is to have a force sensing resistor (FSR) that can measure if excessive force is applied on it and alert the instructor.

IV. Implementation

A. Cannulation Pads Fabrication

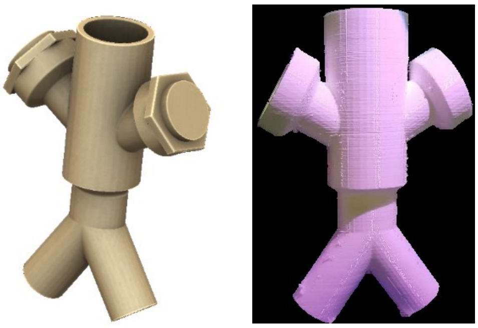
The process of making the cannulation pads from the mould as seen in Fig. 3 begins with the mixing in equal quantities of two chemical liquids that solidify when mixed in the presence of air and form the silicone rubber. Die can be added to give it a skin like color. Once mixed very thoroughly, the liquid needs to be poured into the mold through a funnel. Fig. 4(a) shows the pad after the mould is filled with liquid silicone and Fig. 4(b) shows the pad retrieved from the mold after it was left to solidify for a duration of two hours.

(a) (b)

Fig. 4 (a) Pad in the mold before solidification (b) Pad extracted after solidification.

B. Connectors

A Y-connector needed to be designed and 3D printed in order to connect the tubes of the two veins and allow space for two large cannulas to fit together at the junction and come out into a single tube. Moreover, a screw was designed and added to that Y-connector in a 60 degrees' angle, and that screw will be used to carry the FSR, which will play a significant role in the new system It allows for a new option in the cannulation process whereby the cannula might go into the renal vein and cause internal bleeding to the kidney. The FSR was added to detect if the cannula has missed the main tube and entered the renal vein which is a very common ECMO cannulation issue. The models are shown in Fig. 5.



(a) (b)

Fig. 5 (a) 3D model of the connector (b) 3D printed Y-connector.

C. FSR Circuit

For the initial setup of the FSR in the circuitry, the component is connected to the microcontroller with a 10kΩ resistor, thus allowing the microcontroller to supply the voltage for it to power and acquire data trials through the sensor. The FSR circuit was implemented in the venous loop system by testing the guidewire entry into the renal vein as a procedural emergency and is shown in Fig. 6. The LED turns on when the guidewire touches the FSR, indicating that the clinician has entered the wrong path. Fig. 7 shows the LED activated when the guidewire is inserted through the cannulation pad till it reaches the IVC.

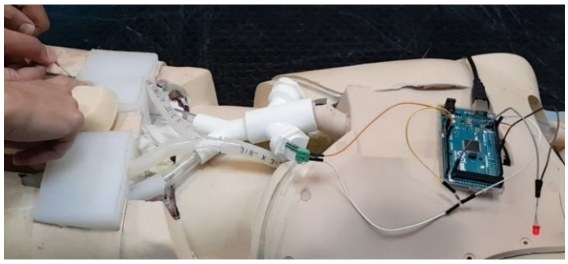


Fig. 6 FSR circuit implemented in the venous loop.

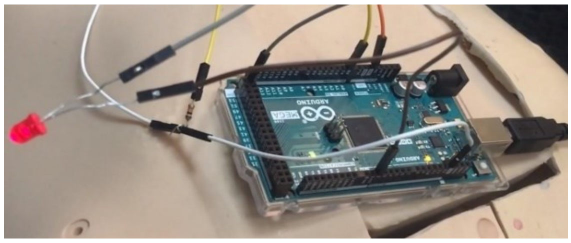
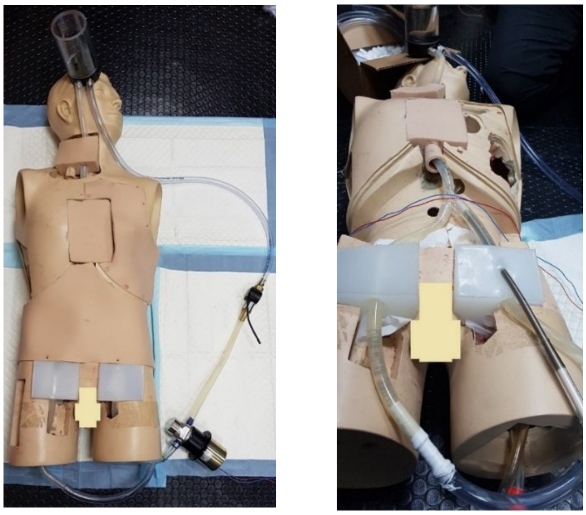


Fig. 7 LED activated when the FSR detects guidewire entry in the renal vein.

D. System Integration

After performing the implementation and testing of all subsystems, they were integrated into the mannequin as one whole system for final implementation and testing. Initially, the mannequin received from HMC was fitted with pads and tubes for basic ECMO training. Fig. 8(a) shows the mannequin with the updated changes while Fig. 8(b) shows the mannequin with the cannula successfully inserted into the pad of the left femoral artery with the assistance of the guidewire.



(a) (b)

Fig. 8 (a) Mannequin with implemented system (b) Arterial loop with cannula inserted in the left femoral pad.

V. Conclusions and Future Work

Beyond addressing HMC's need for an ECMO simulation platform for local training purposes, this project generally aims to provide a better technological solution for immersive ECMO SBT. Our training system features multiple blood flows in two different interconnected loops simulating venous and arterial circulation. A defining feature of the arterial system is the circulation of liquid caused by a pump that simulates a pulsatile flow. This pulsatile flow also allows a pulsing vibration effect on the arterial cannulation access point pads which can be felt by touch.

The system will allow for creating various procedural emergencies especially in real-time operation/procedures such as cannulation or VA to VV-A ECMO transition through the use of sensors strategically placed in the system. The embedded system and sensors will allow simulation for procedural emergency alerts such as bleeding, excessive force applied to the renal vein, wrong wire/cannula placement, and hemorrhaging. The cannulation pads offer a realistic feel due to their flesh-like ultrasoundable material and they are cost-effective to produce using the molds which have been designed. This system allows for realistic and repeated cannulation training. More training modules can still be developed after system testing of the latest prototype by HMC ECMO clinicians. It is also worth mentioning that the current cost of the simulator is about $580 which is much cheaper than the ones in market. Ultimately, the development of this comprehensive and modular ECMO training system focuses on both providing a highly realistic cannulation and ECMO patient management experience that will pave the path towards a revolution in ECMO training.

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