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ORIGINAL ARTICLE

Design and development of a lower cost, customizable simulator for resuscitative endovascular balloon occlusion of the aorta (REBOA) training

Axel B. Lichtenberg,[a,*] Joseph Weinberg[b] and Frank Bauer[b]

[a]*William Carey University College of Osteopathic Medicine, 710 William Carey Parkway, Hattiesburg, MS 39401, USA;*
[b]*HonorHealth, 7351 E Osborn Rd Suite 200B Scottsdale, AZ 85251, USA*

**Corresponding author at: 710 William Carey Parkway, Hattiesburg, MS 39401, USA. Email: axel.lichtenberg@gmail.com*

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Abstract

Background: The increasing utilization of endovascular techniques for managing traumatic hemorrhages, particularly resuscitative endovascular balloon occlusion of the aorta (REBOA), underscores the need for effective training tools. Traditional training methods, often high stress and time sensitive, necessitate the development of realistic, accessible simulators. The objective of this study is to develop a REBOA simulator that accurately simulates the entire procedure, and is highly portable, low-cost, and reusable. **Methods:** A novel, cost-effective REBOA and endovascular access simulator, termed the Training Resuscitative Endovascular Balloon Occlusion of the Aorta (TREBOA) system, was designed, constructed and evaluated. The system was tested by calculating physiological blood flow and pressure drops using Reynold's number, and assessing the gear pump's flow rate at varying voltages. A failure mode effects analysis was also conducted to evaluate safety and reliability, with adjustments made for issues exceeding the defined risk threshold. **Results:** Extensive testing confirmed the simulator's efficacy in replicating realistic physiological flow and pressure responses. Safety and reliability assessments indicated a low risk of operational hazards, with the total construction cost being significantly lower than existing simulators at approximately US$1000. **Conclusions:** The TREBOA simulator offers several advantages over current models, including cost-effectiveness, anatomical and procedural fidelity, and the potential for customization. Its design facilitates a wide range of training scenarios, from basic skills to complex procedures, making it an invaluable tool for medical practitioners. This innovation holds promise for expanding access to high-quality training in REBOA and endovascular techniques, ultimately enhancing patient care in trauma settings.

Keywords: *REBOA simulator; endovascular training; traumatic hemorrhage management; medical education technology; cost-effective medical simulation; ultrasound-compatible simulation*

Introduction

There is an expanding interest in the use of endovascular techniques for both blunt and penetrating abdominal trauma, fractures with pelvic hemorrhage, or ruptured abdominal aortic aneurysms. Endovascular techniques confer several benefits, including decreased morbidity and reduced length of hospital stay, as well as quicker return to functional daily life.[1] In situations of aortic hemorrhage, resuscitative endovascular balloon occlusion of the aorta (REBOA) may be indicated[2,3] and this technique is being promulgated for refractory hemorrhagic shock below the diaphragm. REBOA was first developed in the 1950s for the Korean war[4] and is being increasingly used to quickly and effectively stop traumatic hemorrhage.[5,6] Currently, certain difficulties exist in learning this technique. Specifically, one needs to learn how to reliably gain rapid femoral artery access and then effectively manipulate a catheter device into an adequate anatomic position for deployment. Historically, surgical training has consisted of progressive, graded practice on patients. In this case, deployment of an endovascular device diverges from routine general surgical and trauma practice enough to require targeted and specific training for practitioners to gain reliable competence. Training in endovascular access and technique outside of clinical practice is necessary, especially in traumatic hemorrhage, as these situations are time sensitive and are performed in high-stress situations.[7]

Therefore, there have been increased efforts to create simulators on which medical practitioners can learn this

technique.[8] Vascular surgeons are increasingly using simulation training, as it has been shown to improve proficiency in technique,[8,9] and may be more effective for those in the early stages of their training.[10] Simulation-based training enables the trainee to learn these techniques free from the intense pressure of real-life consequences. Critically, the training can be directly mentored at varying paces with immediate feedback at the point of a procedural error and is able to provide objective feedback on performance in order to ensure a minimum level of proficiency.[9,11] There are a few courses located in the USA, including the Basic Endovascular Skills for Trauma (BEST)[12] course, and the Endovascular Trauma and Resuscitative Surgery (ESTARS)[13] course. These programs provide didactic and instruction sessions coupled with a variety of endovascular training simulations. However, access to these courses is often restricted by location, time, and cost constraints.

Previous studies on simulated training have demonstrated improved proficiency at varying levels of experience.[14] Training can therefore be employed earlier in one's education, facilitating the development of basic skills such as wire and catheter handling skills, such that the more complex components of the procedure are likely to be subsequently learned more expeditiously.[9] Previous work has shown that a synthetic model can be created that is able to simulate pulsatile blood flow and physiologic responses to balloon insertion and inflation.[15]

There are, however, certain aspects of previous simulators that can be improved upon, namely anatomical and physiological realism, portability, reusability, learner throughput, and cost. Existing REBOA trainers including Medalus, PerfusionSim, and Prytime all provide simulation experiences with appropriate anatomical and physiological realism as compared with our simulator (see Supplementary Table 3 and Supplementary Table 4). However, in comparison, our simulator is less expensive and provides access to both groins with physiologically accurate pressure and flow measurements. Considering this need for physiologic accuracy at a lower cost to trainees, we developed an anatomically and physiologically realistic, highly portable, reusable, and inexpensive REBOA simulator that is able to simulate the entire REBOA procedure, from gaining access to both left and right femoral vasculature to balloon expansion and cessation of blood loss. Furthermore, we demonstrate that the use of 3D printing is able to realistically create components of the training simulator. The ultimate goal of the TREBOA system is to enable the expansion of access to highly realistic REBOA training.

Materials and methods

Training simulator layout

The TREBOA training simulator is designed around a mannequin modeled around the physique of a male in his twenties, composed of plastic to ensure a sturdy system with ease of transport (Fig. 1). The mannequin is stabilized via bolting to a black laminate board via holes drilled in the shoulders and buttocks. The chest can be opened in order to inspect balloon placement following insertion and inflation. The groin region is removed from the mannequin to facilitate the placement of the training simulator groin. Latex-coated Styrofoam and wood are used within the mannequin in order to support the tubing and internal components, as well as to create a level surface for the shoulders and buttocks. The aorta is secured to the Styrofoam via conduit clamps. The Styrofoam support is positioned in such a way as to raise the system and minimize the development of air bubbles.

A reservoir capable of holding 1 L of liquid is bolted to the top of the mannequin to supply the fluid for the TREBOA training simulator. This reservoir has an inlet valve connected to the end of the closed-fluid system, an outlet valve leading to the fluid pump, and an air relief valve to prevent the development of a vacuum. A water-proof wooden box is created and placed in the mannequin in order to contain the pump, a solenoid valve, and the electrical components of the system. The box is supported in such a way as to keep the pump level within the system.

An internal, electronically controlled positive displacement gear pump is used in order to generate a continuous fluid flow regardless of resistance, generating clinically appropriate pressure changes, i.e. correct balloon placement and inflation. The fluid pulsations and pressure changes mimicking human blood flow are generated by way of a prescripted pulse width modulation (PWM) code fed into a microcontroller (TI-MSP430F5529) that regulates a motor control circuit to drive the gear pump.

The progression of fluid throughout the TREBOA training simulator involves a closed system of fluid flow including the reservoir and a series of silicone tubing and connectors, effectively simulating the vasculature system involved in traumatic hemorrhages for which REBOA is indicated (Fig. 2). The vein system is filled with blue-colored water (therefore visibly different from the arteries); however, this only consists of a short portion of vein within the ultrasound compatible groin. Once the gear pump is started, fluid begins to flow from the 1 L reservoir into silicone tubing leading to a T-connector, with one path leading to the pressure sensor and the other progressing through the system. The fluid then passes through two couplers to transition from the 3/16-inch inner diameter (ID), 3/8-inch outer diameter (OD) silicone tubing to the 1-inch ID, 1-1/4 inch OD acrylic aorta; the first coupler increases the tubing diameter from the 3/16-inch ID tubing to 3/8-inch

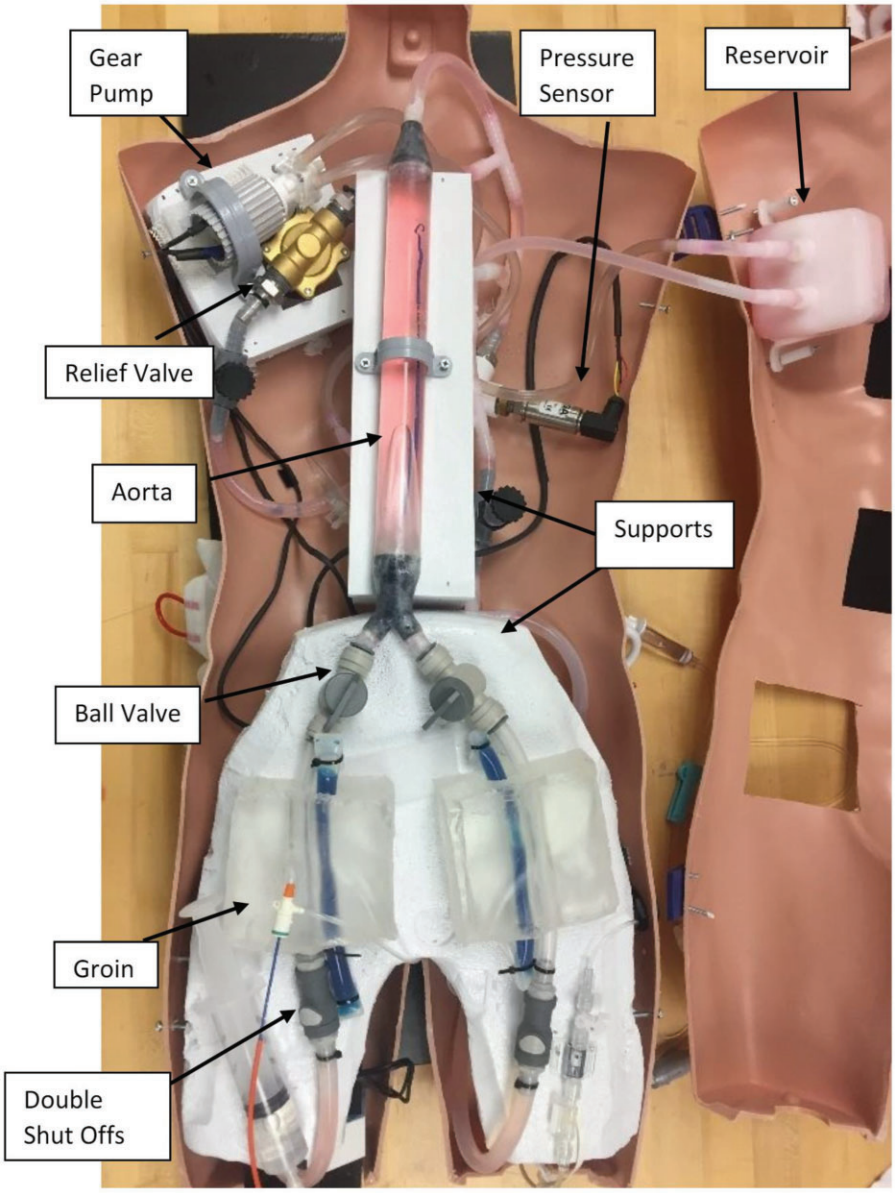

Figure 1. Final design solution for TREBOA showing internal components and layout beneath external casing.

ID tubing, and the second coupler is custom-made and is secured with epoxy and flex sealant that increases the ID from 3/8-inch ID to 1-inch ID to match the diameter of the aorta. Between these two couplers is attached separate silicone tubing leading to a relief valve containing a needle valve to manually tune the pressure to healthy values and then to the tubing returning from the groins; the fluid otherwise progresses through the second coupler on the way to the aorta.

Following passage through the aorta, the fluid flows to a customized 3D-modeled bifurcation that reduces the 1-inch ID of the aorta back to the 3/8-inch silicone tubing leading to the groin areas (see Supplementary Fig. 1). A ball valve is placed at the top of the bifurcation to allow for passage of the catheter without obstruction as well as to ensure no fluid loss occurs upon groin block removal. The fluid then flows to the groin areas leading to a T-connector to silicone tubing containing a needle valve that serves to tune the system

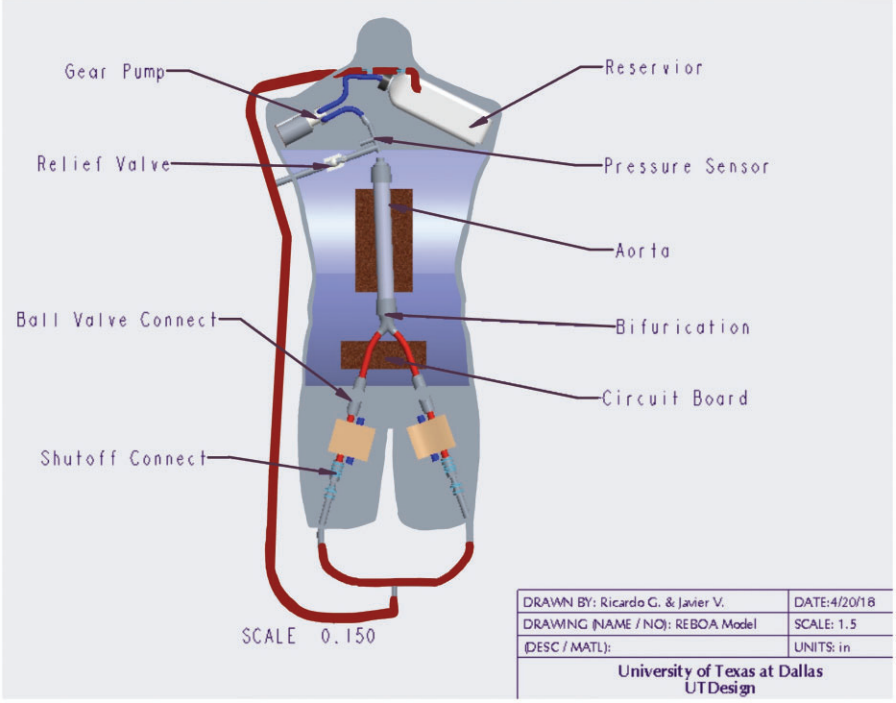

Figure 2. Component detailed full body schematic. Design layout demonstrating the tubing support. Styrofoam and wood were used to raise the tubing and internal components, as well as to create a level surface for the shoulders and buttocks. All the Styrofoam was coated with a latex paint to prevent the Styrofoam from breaking down. The aorta was attached to the Styrofoam using conduit clamps. In order to fill the system upon startup with minimal air bubbles, the aorta was raised by adjusting the height of the Styrofoam supports to create a slight incline. The effect on pressure this incline had was negligible, but air was able to flow out of the aorta tubing. Reproduced with permission from University of Texas at Dallas UT Design.

to the desired pressure of 70/40 mmHg at the beginning of the simulation. This progresses back to the reservoir by way of double shut-off quick connectors ensuring no fluid loss upon groin removal.

Groins

Removable, reusable groins are created to fit the groin region of the mannequin using Humimic liquid ballistic gel (Humimic Medical, South Carolina). This gel is highly reusable, as it can be melted down and recast in a matter of minutes. Critically, the gel is highly compatible with ultrasound imaging, an important component of the REBOA procedure. The process of creation of the groins is as follows: 1) a custom wooden box is created consistent with the required specifications of the groin region of the mannequin, 2) the previously removed plastic mannequin groin is placed at the bottom of the box to facilitate proper curvature, 3) the silicone tubing is then situated in the box, secured in place via zip ties and holes in the box, 4) the gel is liquefied by heat and then poured into the box and allowed to set, and 5) the set gel block is then shaved to fit the necessary specification of the mannequin groin regions. The gel block is placed on Styrofoam in order to keep the groin level with the rest of the system. Device testing demonstrated an average exchange time of 30 s with < 1 ml system fluid loss. Images of the computer-aided design (CAD) schematic of the groin and of the real piece within the device are shown in Supplementary Fig. 2.

Electrical components

Pressure sensor

A pressure sensor (range 0 to 5 psi, output 0 to 5 V) is used in order to monitor the fluid pressure within the system. The pressure sensor specifications serve to detect the small pressure changes (0.77 psi to 2.12 psi) encountered during the procedure. Data from the pressure sensor are fed into the microcontroller in order to generate the appropriate pressure responses during the simulation.

Simulation buttons

A toggle switch is connected to the battery and electronic components in order to provide power to the device. Upon turning the switch on, the system enters an idle state wherein fluid from the reservoir fills the system. A second

button is used to begin the simulation, starting the system pressure at 70/40 mmHg to mimic a patient experiencing severe blood loss. The pressure will then reduce to zero over the course of 7 min without adequate REBOA intervention.

Battery

Power to the TREBOA system is supplied via a battery encased in a custom-made 3D-printed box in order to avoid damage from fluid during the procedure. A window is included in the box in order to visualize the charge indicator and the charging port.

Results

TREBOA system testing

Several steps were taken to verify the efficacy of the system in simulating a patient experiencing hemorrhaging for which the REBOA procedure is indicated. First, the fluid flow throughout the system was tested to ensure a realistic simulation of physiological flow of blood in a human patient. Realistic flow and pressure drops were determined by calculating the Reynold's number. Flow-rate data from the pump showed that there was an exponential correspondence between the flow rate and system pressure. These calculations can be found, along with additional information showing the outline for the fluid system, in Supplementary Table 1 and Supplementary Fig. 3, respectively.

Next, the efficacy of the gear pump was tested in several ways. First, in order to ensure that the rate of flow can be changed by way of varying the input voltage, a container was filled with water, into which the ends of tubing from the gear pump were placed. Upon providing power to the pump at various voltages, the tubing was moved to a marked empty container. The time to fill the container to the set point was then determined. This demonstrated that there was an exponential relationship between the voltage and rate of fluid flow (Fig. 3). We subsequently tested the effectiveness of the microcontroller in regulating the gear pump to create realistic pulsations of the tubing with changing flow rates. The tubing was connected to the circuit powered by the DC power supply (10 V, 2 A), and a current-limiting diode was connected to the microcontroller. With the initiation of power to the setup, pulsations in the tubing were visualized. Critically, the coding to the microcontroller effectively decreased the pulsations over time, mimicking a patient undergoing severe blood loss. Finally, we tested the ability of the pressure sensor to detect and report changes in system pressure. It was found that the pressure sensor was able to read out changes in pressure, and that pressure decreased over time without intervention.

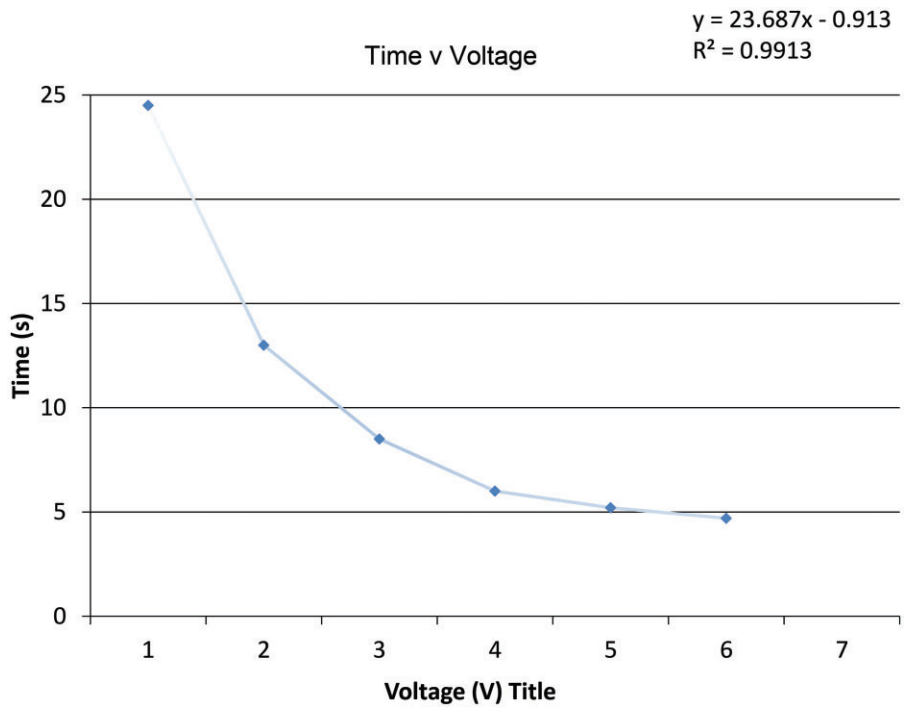

Figure 3. Time vs voltage for pump system, showing an exponential relationship between increasing voltage and the amount of time it took to fill up the bottle.

Table 1. Failures with RPN ≥ 100 and implemented action plans

Component	Failure mode	Cause	Occurrence	Severity	Control	Action plan	RPN score
Solenoid valve	Closed	Pressure sensor inaccurate	6	6	6	Multiple tests to ensure the pressure sensor is accurate and implementation of hysteresis window	216
Couplers	Leak/disconnection	Incorrect adhesion	6	4	6	Multiple tests prior to building final prototype to ensure adhesion is correct	144
Bifurcation	Leaks	Incorrect adhesion	6	4	6	Multiple tests prior to building final prototype to ensure adhesion is correct	144
Gear pump	Pump casing overheats	Pump runs for too long	8	5	5	Add a notification if pump has been on for too long	200

Table includes components, failure modes, causes, action plans, and risk priority number (RPN) scores for all instances where the RPN was greater than 100 and an action plan was implemented. These were derived from the failure mode effects analysis performed on the simulator device.

Safety, reliability, and cost

The TREBOA system was determined to be very reliable for use. This was done by ranking the occurrence, severity, and control in the context of several scenarios (Table 1). Three scenarios were found to be potentially troublesome for the system. First, there is the potential for the gear pump to run dry if it runs for too long, leading to overheating. This is considered the only potential safety hazard to the user. The easily accessible power switch enables quick cessation of the simulation in the case of any overheating. A notification was also added to warn if the pump has been on for too long. Next, there is the potential for insufficient connectivity of the couplers and/or connectors, leading to the possibility of fluid leakage. Rigorous testing of the couplers, connectors, and their adhesives over a wide range of conditions was conducted, demonstrating that these components were robust. There is also a possibility of failure of the components and valves, leading to a buildup of pressure that may cause problems such as bursting connections and rupturing of valves and/or the pump's internal seal. This concern was alleviated by rigorous testing of the system across a range of possible scenarios until the issue was resolved. The implementation of a hysteresis window was performed to allow for the visualization of the fluid in the reservoir, and sensors were tested. Further information on compliance testing of the device can be found in Supplementary Table 2. The total cost of the construction of the TREBOA simulator system was US$1094.63, with the largest share of the cost going to the electrical transducers. Notably, the gear pump can be obtained for ∼US$72.

Discussion

Cost

Endovascular interventions are increasingly deployed to stabilize individuals that are experiencing severe hemorrhage.[16] Traditionally, REBOA training has been conducted via progressive exposure and practice in real-life situations. This complicates the learning process, as the situations in which REBOA are used are generally high stress and highly time sensitive. Various training methods have been developed to help address these concerns by way of simulation of the procedure.

As mentioned above, there are a few courses located in the USA, including BEST[12] and ESTARS.[13] These courses provide didactic and instruction sessions coupled with a variety of endovascular training simulations, predominantly via the use of perfused cadavers, VR devices, and animal models.[12,13] However, each of these have their particular weaknesses.[7] The cadaver model is a single-use procedure, is not portable, and requires a high cost to conduct. VR models, while re-usable and portable, involve very high costs and are less similar to real-life situations. Finally, animal models are single-use procedures, involve differences from human anatomy, specific facilities, and are also high in cost.

Synthetic biomechanical simulators are gaining interest as a way to address these short-comings. A previous synthetic model was developed by Keller and colleagues.[15] This system consists of a vascular circuit simulating the abdominal aorta, iliac bifurcation, common iliac arteries, and common femoral arteries supplied by an external pulsatile perfusion pump. There are certain aspects of this system, however, that can be improved upon. Specifically, the pump is situated externally, complicating its portability. Only one of the femoral arteries is available for access, as the other is used for pressure monitoring. The gel-based groin mold can be used only four times before needing to be fully replaced. Finally, the cost, while lower than other simulators, is quite high (∼US$11 000).

Another synthetic biomechanical simulator was recently developed by Dr. Christopher Kinsella, the Medalus REBOA

Table 2. REBOA simulator cost comparison with other currently available REBOA simulation options

REBOA trainer type	Cost (US$)	Parts replaceable	Reusable	Both groins accessible	Requires external power source
TREBOA	$1094	Yes	Yes	Yes	No
Medalus REBOA[22]	$7995	Yes	Yes	No	No
PerfusionSim[19]	$23 186	Yes	Yes	No	Yes
Keller Study[15]	$11 000	Yes	Yes	No	Yes
Prytime[20]	Presumed high[a]	Yes	Yes	No	Yes
Walsh Study[18]	Presumed low[b]	Yes	Yes	No	No
VR	Presumed high	N/A	Yes	N/A	No
Syndaver[21]	Presumed high	Yes	Yes	Yes	Yes
Cadaver	Presumed high	No	No	Yes	Yes
Animal	Presumed high	No	No	Yes	Yes

[a]Cost estimated to be >US$10 000 based on available information and requirements for use.[23,24]
[b]Cost estimated to be <US$100 based on available information.[18]
N/A: not applicable.

Task Trainer.[17] This model, while provided at a lower cost (∼US$7995), does not contain a pump in its system and also only has one femoral artery available for access. The lack of a pump allows this model to be more portable, but loses some of the important haptic feedback allowed by other models.

An inventive and cost-conscious approach was undertaken in the development of a REBOA simulator, conceptualized by researchers for use in an Emergency Medicine conference by resident physicians.[18] This model was engineered as a budget-friendly alternative, employing commonplace materials such as a bicycle tire inner tube to represent the aorta and rubber tubing for the femoral artery. Although this simulator lacked a pump system to offer precise feedback and was unable to facilitate access to both groins simultaneously, its design was pragmatic. Despite its simplicity and lacking certain features, this model demonstrated the REBOA procedure, achieving significant cost savings compared to conventional simulators by utilizing easily accessible components. A detailed cost and feature comparison is included in Table 2.

The goal of this work was to create a simulation device to simulate the entire procedure from access to placement to withdrawal of the device. This required the device to be extremely functional with ultrasound and tailored for a high throughput of learners. We also wanted a self-contained device including the physiologic pump and power source. All of this was to be accomplished at a fraction of the cost of previous works. We also wanted a device that could be customized allowing future simulation professionals to add on further functionality (e.g. coiling simulation or EVAR).

Our TREBOA training simulator confers several benefits over previous simulator models. Key innovations include a gear pump to drive physiologic pressure, truly exchangeable groins and the use of custom 3D-printed parts. The construction and layout of the system is a more realistic representation of human anatomy and physiology, including both left and right groin access that can be used simultaneously. The TREBOA simulator is therefore able to simulate clinical scenarios where bilateral groin access is required. Whereas other synthetic simulators have vascular access already in place, our training model begins with the need to access the femoral arteries, as one would need to do in real-life situations. The gel is also highly compatible with ultrasound, a critical component of the REBOA procedure. Fluid flow throughout the system is electronically controllable by way of custom coding fed into a microcontroller and is thus able to simulate pulsatile flow over a range of rates and pressures. Upon initiation of the simulation, the fluid pressure begins at pressure levels consistent with a patient experiencing hemorrhagic shock, dropping to zero over the course of 7 min without intervention. Upon deployment of the balloon, fluid pressure returns to a healthy stable range, consistent with successful performance of the procedure. All together, these advancements enable the TREBOA system to provide the trainee a highly realistic simulation of a human experiencing traumatic hemorrhagic shock and the successful deployment of the REBOA procedure.

In addition to this highly realistic simulation, TREBOA has several other advantages over other simulators, including reusability, portability, and cost. TREBOA is highly reusable, as the groins can be reused up to 15 times before being replaced, and the Humimic ballistic gel can be melted and recast in a matter of minutes. The groin system therefore enables the training of multiple individuals in a single session. TREBOA is also very portable, as all components are placed internal to the mannequin and can be transported in a single container. This also means that, as the gear pump and fluid reservoir are internally placed, there is no need for

external fluid containment and flow. Another significant advantage of TREBOA is the cost of construction, as the entire system can be built for approximately US$1000. Another unique aspect of the TREBOA system is the use of 3D printing for several of its components. Our developmental process showed that 3D printing can be effectively used to recreate human anatomical structures. The use of 3D printing has been expanding greatly over recent years due to its increasing availability and decreasing costs. This means that the TREBOA system can be recreated relatively easily at a rather low cost. Finally, TREBOA does not require specialized facilities and is free of ethical concerns related to cadaveric simulations. Taken together, our simulator provides the capability to greatly expand access to realistic training on the REBOA procedure. Additional information regarding the availability, raw materials, safety, reliability, and efficiency of available REBOA simulators is also included in Supplementary Table 3 and Supplementary Table 4.

There are several limitations to our simulator. Through the development of this simulator, we sought a middle ground between simplicity in design and fidelity to real-world conditions. Due to the presence of a motorized pump system, user error resulting in the pump running for too long was shown to cause overheating and potentially damage to the system. Furthermore, on failure testing, there were some occurrences of over-pressurization due to clogged inlet and outlet systems that required users to monitor the system during use. Though there is a relatively high fidelity between the anatomic design of our system and human anatomy, our design size is constant, and therefore anatomic variability cannot be accommodated. A summarization of the simulation failures with the highest risk priority numbers (RPNs) and the implemented action are included in Table 1. Additional limitations include lacking evidence of user feedback as the simulator has yet to be employed in a real-world simulation session with larger numbers of healthcare workers. This would be an excellent next step for future testing.

In summary, TREBOA is a realistic simulation of a patient dying from hemorrhagic shock. Critically, the TREBOA trainer system is self-contained, portable, reusable, and customizable while maintaining anatomic and procedural fidelity. Future directions could include customizing the simulator to simulate more advanced scenarios such as EVAR or coiling.

Supplementary material

Supplementary Figures 1–3 and Supplementary Tables 1–4 are available at https://doi.org/10.5281/zenodo.13767089.

Conflict of interest

The authors have no conflicts of interest to declare.

Data availability

Data supporting the findings of this article are included in the article and the Supplementary Material. Further data supporting the findings of this article are available from the corresponding author on request.

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