RediStik™ ECMO Cannulation Trainer Proof-of-Concept Design and Implementation

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Background

Extracorporeal membrane oxygenation (ECMO) is a high-risk low-frequency emergency procedure.
A needs assessment performed on pediatric ECMO cannulation identified a significant need for a low-cost and realistic ECMO cannulation trainer that would enable surgical and perfusion teams to perform all steps in Neck ECMO cannulation, providing more versatile training options.

Goals/Objectives

- Develop a realistic and inexpensive Pediatric ECMO Cannulation Trainer
- Pilot/survey the proof-of-concept obtaining user feedback on the finalized trainer and skills video
- Evaluate survey data from pilot; modify educational tools and share

Methods

The project team incorporated innovation processes, interdisciplinary collaboration, user feedback, and quality improvement tools to develop a novel Pediatric ECMO Cannulation Trainer program

Proof-of-Concept (POC) Development Process

Phase 1: Discover and validate the "need"
- Need validated by surgery, sim center, and perfusion
- Identified potential quality improvement goals

Phase 2: Investigate available/utilized products
- Explore ways a "need" can be solved **without creating a new product**
- Project goals not readily available on the market - therefore progressed to new product development

Phase 3: New product development – user feedback
- **Prototype iterations to finalize design:**
  - 3 hearts, 4 necks, 3 vessels, 3 base holders
- **Videos utilized for fabrication documentation, sharing and skills video development:**
  - *Video equipment: GoPro 7 w/head strap on surgery fellow, Google Pixel w/gimbal*
  - *Video while testing multiple prototypes. Helped with design documentation. Footage used to develop ECMO cannulation teaching video used in pilot*
  - *8 design recommendation videos to* **Sawbones©** Design Engineer
    - **Videos explaining key design goals** are an important communication tool

## Phase 4: New product pilot and survey
- Pilot/survey final prototype and skills video with **Perfusion team, Pediatric General Surgery and Pediatric Cardiovascular Surgery** at Texas Children's Hospital
- Pilot provided valuable feedback to **finalized design and set-up instructions.**

Results
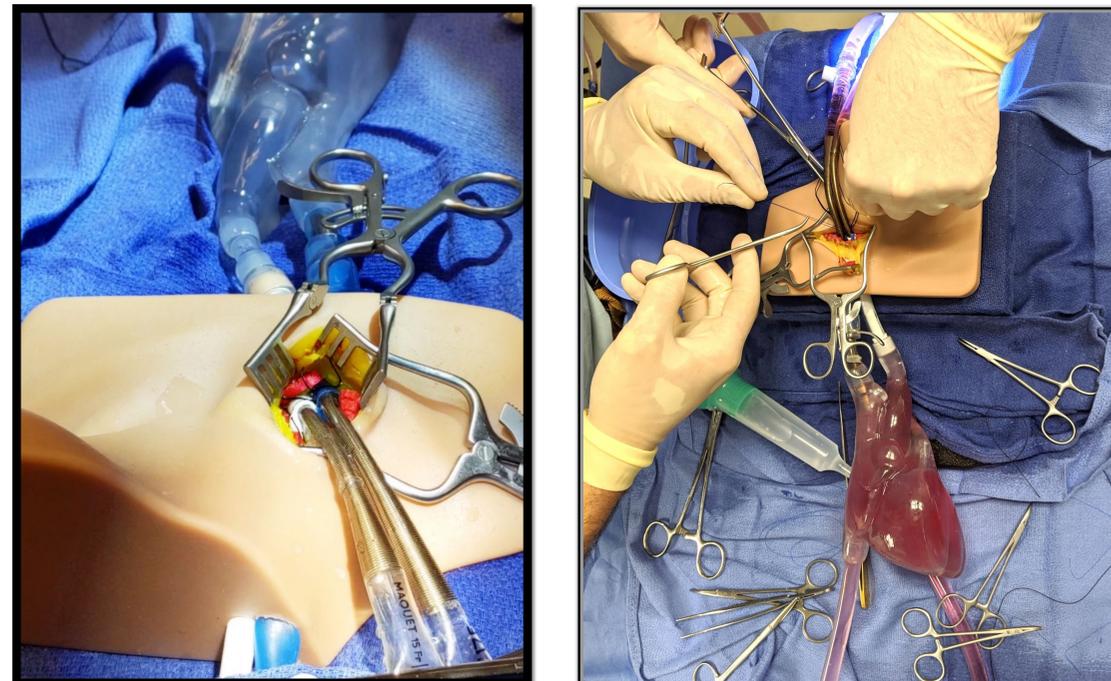### RediStik™ ECMO Cannulation Trainer Design

NECK SIMULATOR (SINGLE USE)
- Right side of neck with **anatomically accurate landmarks** (mandible, clavicle, SCM).
- **Realistic tissue layers** (skin, fat, platysma, SCM) for cutting and spreading to expose the vessels: (SCM can be spread, cut, encircled, or laterally retracted to expose vessels)
- **Correct neurovascular (IJV/Carotid/vagal nerve) positioning, color and feel** allows for accurate exposure, cutting, applying traction sutures/tourniquet to control the vessels, and cannula insertion.
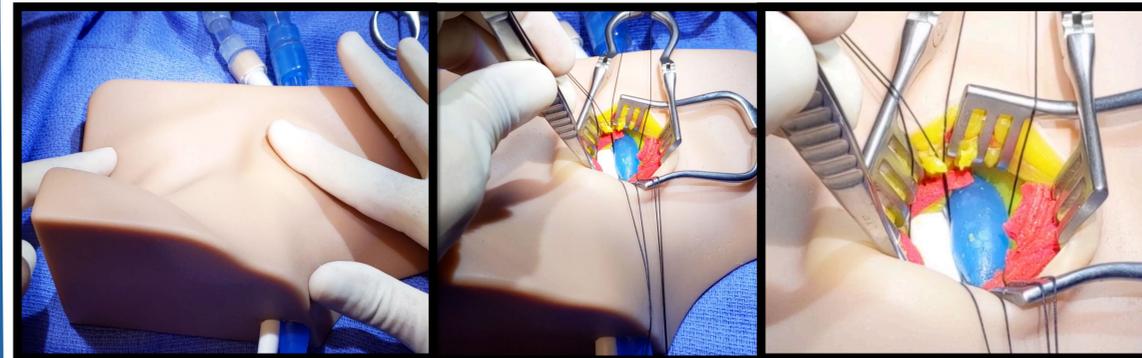
HEART (REUSABLE DESIGN)
- Transparent heart provides visualization during insertion of the cannula.
- Provides closed loop system to connect to the ECMO circuit.
- An elevated liter bag of saline creates pressure in the system to allow for realistic "bleed back", so a pulsating pump is not necessary.

Quality/Innovation Process Results

Project outcomes vetted a step-wise innovation process to develop and implement the **RediStik™ Pediatric ECMO Cannulation Trainer proof-of-concept** using innovation processes/tools, inexpensive technology, and skills videos.

Measurable outcomes by implementing project:
a) Improve surgical competency and efficiency in ECMO cannulation
b) Increase surgical/perfusion competency, safety, and efficiency in connecting to the ECMO circuit
c) Develop new concepts to incorporate the design into simulation scenarios
d) Develop and standardize simulation tools
e) Produce skills video demonstrating cannulation and connecting to the ECMO circuit.

Preliminary pilot results:
100% (n = 6) of Pediatric CV/general surgeons rated good/very good on effectiveness for practicing VA ECMO cannulation and connection the ECMO circuit.

100% (n = 6) of Pediatric CV/general surgeons recommend the RediStik™ ECMO Cannulation trainer for skills validation to their colleagues.

Phase 5: Implement and Share
- Complete pilot March 2021
- Implement ECMO Cannulation Simulation Program
- Incorporate **RediStik™ ECMO Cannulation Train**er into systems testing and ECPR simulation
- *Open source* videos, lessons learned and pilot data

Conclusions

Design, development and implementation of the **RediStik™ Pediatric ECMO Cannulation Trainer** has produced valuable outcomes and opportunities to share lessons learned. The project demonstrated a multidisciplinary approach to develop novel simulation training opportunities for front-line staff. The realistic, versatile, cost-effective and reproducible Pediatric ECMO Cannulation Trainer design partnered with the skills video sets it apart from existing ECMO trainers. We anticipate the novel trainer will positively impact our pediatric patients and staff as well as learners in the United States and other countries. **The skills videos are open source and the RediStik™ ECMO Cannulation Trainer kit is available for purchase globally.**

References

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