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SURGICAL LVAD IMPLANTATION SIMULATOR

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ABSTRACT

The mission of P10023 is to design and develop a working 1:1 replica of a human thoracic cavity to use as a surgical training device for implanting a left ventricular assist device (LVAD). The simulator was designed to mimic the size and look of an average human torso from the neck to the abdomen, with ribs, fake lungs and diaphragm, and a fluid system to attach to a pig or calf heart to mimic blood flow. Customer needs were gathered from both the project's advisor and funder, Dr Steven Day, and from the leading LVAD surgeon at Strong Memorial Hospital and the Clinical Coordinator, Dr Todd Massey and Bill Hallinan.
The final product incorporated many features from benchmarked products and ideas of the sponsors, and has the necessary functionality to train surgeons on the procedure of cannulation of the heart and implanting the VAD.

BACKGROUND

The use of ventricular assist devices has become more and more popular in the medical industry. LVAD's are implanted in a human's chest, connecting to the heart and aorta. It assists the left ventricle of the heart in pumping blood to the body for a person that has a weakened heart. This device has been used to save many lives and provide additional time for those awaiting a heart transplant.

The implantation of the LVAD device isn't a standard surgery. Not many surgeons are trained in this area. The surgical implantation of a left ventricular assist device requires, among other things, the cannulation (cutting a hole) in the left ventricle for connection of the inlet tube of the pump, and proper placement of this cannula within the ventricle. Figure 1 depicts portions of this process [1].

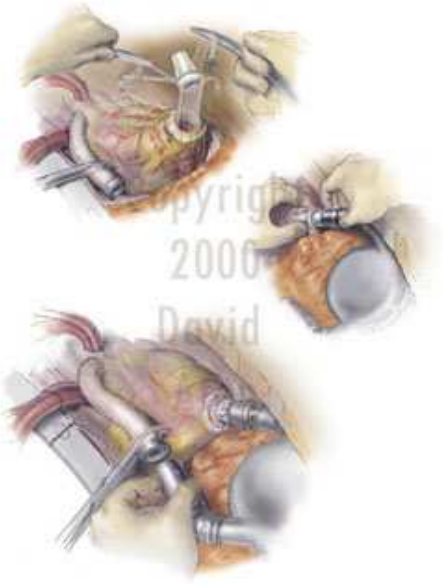

Figure 1: Illustrations of the LVAD Implantation Surgery

The current practice for training for the implantation of an LVAD is to perform this cannulation on non-pressurized pig hearts sitting in a metal tray and then on a very limited number of live animals.

The trainer in use now at Strong Memorial uses an aluminum frame, with hinges and springs attached to upright, rib like structures [2]. There are four of the

uprights, essentially creating a very unrealistic version of a ribcage. The surgeon being trained with this device has a heart placed on a tray inside the "rib cage," with every vessel that is not sutured to a fluid reservoir being sutured shut, causing the heart to slightly pressurize. The problem with the method is in the fact that the heart is in an unnatural flaccid state, and loses a large amount of fluid during the training. The length of setup time required since every vessel must be sutured is an issue, as is the unrealistic nature of the training device. The training device has only four ribs, and only the heart is present. The frame is smaller than that of a human thoracic cavity, and the tray holds the frame open. Also, the surgical field is unrealistic in that the surgeons have a full range of view of the heart, whereas in actual surgery, they have a limited view due to the patient's skin etc. The issues with the current trainer were all areas of desired improvement for the customer with the new design.

In benchmarking and researching for the new simulation device, another device was found. The Zurich Heart Trainer is a device used by surgeons practicing or training on coronary artery surgery with a mechanically beating heart [3]. The device was developed in Europe, and is for a different application, however is used in a very similar sense. Many portions of the Zurich Trainer could be applied to a new design for a VAD implantation trainer.

The LVAD implantation simulator was developed with the Zurich Heart Trainer and the UB student's prototype in mind as benchmarks. Some ideas from each were incorporated into the simulator, in an attempt to meet the needs of both Dr Day and the Strong Memorial customers.

PROCESS

To design the LVAD implantation simulator, needs were first obtained from the customers. These included various desires of the customers, including needs that did not directly correlate to an engineering specification. Some notable needs include: a pressurized heart, quick setup and teardown, the trainer should match the average patient and the LVAD is allowed to pump after implantation.

These customer needs were then translated into engineering specifications. This involved additional research to determine what is technically involved within each customer need. Some engineering specifications that correspond to the previously mentioned customer needs are: the heart must be pressurized at approximately 1.55 Psi, the trainer should only require approximately 30 minutes of preparation time before use, the size of the torso should match that of an average patient (generally a male approximately 55 years of age), and the blood flow should be approximately 70 ml/heart beat. All of the engineering specifications combined, meet each customer need obtained. These engineering specifications are what were used as a guideline for design.

Once these engineering specifications were developed, a function tree was created. This function tree provided a graphical representation of what the design of the trainer needed to accomplish. This provided a platform to perform concept selection on the entire system. Based on these functions and previously obtained specifications, concepts were generated. The system that had the ability to fulfill the most customer needs without missing any of the required needs was chosen. The system chosen for the LVAD implantation simulator included a frame, heart, organ tray, abdominal muscle, and two reservoirs (one for waste and one for the fluid that will be used to simulate blood flow). This system decision met various needs including realistic representation of the surgical field that would be experienced, quick setup and tear down, and cleanable.

Once the overall system was selected, it was broken down into subsystems. The subsystems of the LVAD implantation simulator are the control/fluid subsystem, frame/ribs subsystem and the organ tray subsystem. The control/fluid subsystem is the portion of the trainer that provides and maintains pressurization to the heart as well as the proper flow rate to the system. The frame/ribs subsystem is in charge of providing the appropriate skeletal features of the trainer including the appropriate torso dimensions and spreadable ribs. Finally, the organ tray subsystem includes the diaphragm, lungs and abdominal muscle which are necessary to provide the appropriate surgical field.

The process of concept selection, as performed on the overall system, was also performed on the subsystems and even on various aspects of those subsystems (such as material selection). It was using this iterative process, in parallel with continued discussion with people experienced in these areas and analytical calculations, that the entire trainer was designed.

The frame and base (the skeletal features), along with the organ tray, were modeled in SolidWorks. Each piece was modeled individually, and then put together in the respected assembly. There were two sub assemblies, one for the tray, and one for the base/frame. Once the two assemblies were created, they were combined into one overall assembly, as seen in Figure 2.

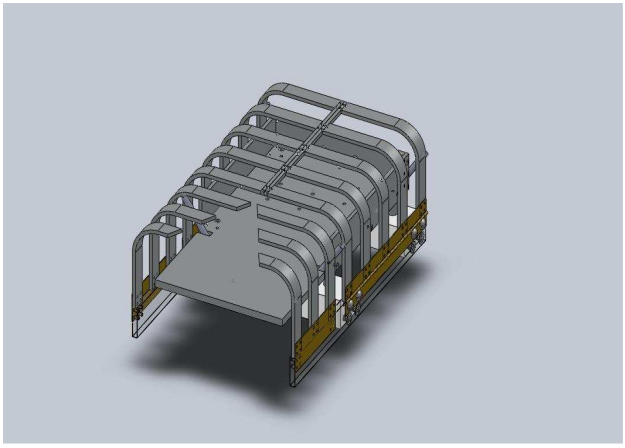

Figure 2: Full Solidworks Assembly

Once the LVAD implantation simulator was designed, building and test plans were created. The following two subsections give more details on these plans.

MACHINING AND BUILDING

Control/Fluid System

The control and fluid system relates to two integrated areas. One is the electrical control unit that controls the flow of fluid to and from the heart, and the second is the mechanical system of pump, tubing, valves and reservoirs which provide the actual flow of fluids. In terms of building, these two systems had different plans.

The electrical control system consists of a data acquisition device (DAQ) and power circuitry. The DAQ is the main portion of the system. A Labview program was to be created to interface with the DAQ to control its inputs and outputs and effectively control the fluid system of the trainer. As its inputs, the DAQ received a pressure sensor (used to determine whether the heart was being maintained at the appropriate pressure) and a fluid level sensor (used to indicate if the system lost too much fluid). As outputs, the DAQ outputted voltage to a linear regulated programmable power supply, which supplied voltage to the DC motor pump in levels proportional to the voltage outputted by the DAQ and adequate for proper operation of the pump, and the fluid level sensor (to allow voltage to go along the switch).

The Labview program scans the pressure and determines whether the pressure is too low or too high. Depending on the current state of the pressure, the program will provide output voltage to the pump to increase, decrease or maintain its current operating speed. This is done to make sure the heart remains pressurized within the allowable tolerance. The program also stops when the fluid level sensor indicates that too much fluid was lost (which in practice is similar to a patient losing too much blood during surgery). Finally, the Labview program allows for the testing of the LVAD. The program slows down the pump providing less pressure to the heart. If implanted correctly, the LVAD should bring the heart back up to the desired pressure range when turned on. The program indicates whether this actually occurs or whether the LVAD provides too much or too little pressure to the heart.

The final part of the building phase for the electrical control system portion of this subsystem entailed the routing of wires. The goal was to make the wires as short as possible, located in generally one area and have easy to use connectors for quick setup and tear down. This portion of the building was to happen once the entire system was interfaced together.

The mechanical portion of the fluid system dealt with a few different areas. The fluid reservoir and the waste reservoir needed to be altered to allow tubing to interface with it. This needed to be done well to avoid leakage. The tubing then needed to be measured and cut to the appropriate lengths to be routed throughout the entire system. Finally, the biggest task of this portion of the fluid subsystem was to prepare the pump and valve. The pump needed to be situated at the appropriate height in the system while the valve needed to be set appropriately to allow the desired pressure and flow rate to the heart. This was to be achieved by trial and error.

Ribs, Frame, and Tray

The aluminum ribs were purchased prior to the other materials and were bent on a bender with a 2 in. diameter. A professional bent the aluminum so that the process was more consistent and reproducible. Holes were then drilled in the base of the ribs using a drill press in order to rivet the ribs onto the hinge.

The ABS and lexan parts of the frame base were machined using a horizontal band saw and drill press, as were all parts for the tray. Exact precision was not needed for many of the parts, so manual machining could be used.

The base of the frame was constructed first, including the drilling of the hinge holes. The following step was riveting the ribs to the brass plates and hinges. The frame was then brought to the RIT machine shop to have the sternum welded on, as well as the springs attached to the first and fifth ribs on each side. The springs provide a more realistic resistance to opening like a human chest would exhibit in surgery.

As the frame was being finished, the tray was machined and assembled. The tray has three walls to keep the fluid enclosed, and nine holes were drilled

under where the heart will be placed so that any excess fluid will drain into a pan. Two holes are drilled into the back wall for the tubing for the heart (inlet and outlet). There are also slots cut into the base of the tray just past the sidewalls so that the springs on the fifth ribs can attach to the ABS base below. Four 2in. legs are attached to the base of the tray, and sit in the holes in the ABS base. 4 mil thick plastic painter's drop cloth is used to simulate the diaphragm on the tray and is attached to the bottom ribs. The plastic is attached using 3M dual lock Velcro. The same Velcro is used to attach the "skin" to the outside of the frame so that the surgeons have a realistic limited field of view during training. The skin is a rubber, silicone sheet, applied in three separate pieces.

Figure 3: Final Chest, Springs Attached, Tray Inserted

TESTING

Control/Fluid System

The fluid subsystem required the most testing of all the subsystems. This required both testing of the electrical portion as well as the mechanical portion.

To test the electrical portion, a DC power supply was used to model the pressure sensor input and a digital multimeter was used to measure the output the DAQ was supplying to what would eventually be the linear regulated programmable power supply to the pump. The DC power supply output was varied to represent different pressure readings the simulator would likely see, and the output of the DAQ was monitored to clarify that it was responding to these pressure readings as intended. This testing was done during the surgery as well as during the "Test the LVAD Pump" phase.

The mechanical portion of the control/fluid subsystem included a few areas. The pressure sensor calibration was to be verified by inducing a known amount of pressure on the sensor and determining if the output produced the appropriate corresponding reading. The pump capabilities were also to be verified. A test program was created in Labview to control the voltage to the DC motor pump. The purpose was to confirm that the pump could indeed provide the desire pressure and flow rate when coupled with a valve.

Entire System

Finally, it was desired to test the entire system together. Due to the lack of easy access to pig and calf hearts, tubing was used to simulate the heart in the system. Although the heart will provide a little more resistance than pure tubing, the results of this test should provide a good base level for verifying the system. The system will be allowed to run as if the surgery was being performed, then as if the LVAD was being tested and finally as if the system lost too much fluid. The final phase of testing after this is to have a surgeon use it in training.

RESULTS AND DISCUSSION

Figure 4: Final LVAD Implantation Simulator

The entire LVAD implantation training simulator system can be seen in Figure 4. The ribs, frame and tray are seen in Figure 3 along with artificial skin attached to it. As mentioned, the diaphragm was simulated by painter's drop cloth and variable packaging balloons were used to create the LVAD muscular pocket in which the LVAD sits after implantation. The lungs were molded out of foam and coated with silicon and the hearts can be attached to the system using hose clamps.

The DC motor pump and reservoirs are located beneath the frame on the middle shelf. Below that, on the bottom most shelf, are the electrical items that compose the control system. This shelf holds the DAQ, linear regulated programmable power supply, isolation transformer and other power chords. Finally, the netbook that has the Labview program and user

interface that the doctors will be using is located on the top most shelf to be accessible like the simulated torso itself.

The control/fluid subsystem test provided the desired results. Figure 5 shows some of the results of the electrical control system component of the testing. As can be seen, the DAQ outputted the desired results for the various inputted simulated pressure sensor readings. The mechanical system tested well too, having both the pressure sensor calibration and pump operation verified.

Control Test Inputs and Results				
LVAD Test?	Pressure(Psi)	Voltage (mV)	Desired Output	Test Results
No	0.1	33.33	Increase Pump Motor Speed	Increase Voltage To Pump
No	0.2	66.66	Increase Pump Motor Speed	Increase Voltage To Pump
No	0.3	99.99	Increase Pump Motor Speed	Increase Voltage To Pump
No	0.4	133.32	Increase Pump Motor Speed	Increase Voltage To Pump
No	0.5	166.65	Increase Pump Motor Speed	Increase Voltage To Pump
No	0.6	199.98	Increase Pump Motor Speed	Increase Voltage To Pump
No	0.7	233.31	Increase Pump Motor Speed	Increase Voltage To Pump

Figure 5: Portion of the Electrical Control Component Test Results

The entire system was combined and verified. All subsystems were able to integrate well. The Labview program controlled the fluid system within the frame and extra tubing that represented the heart. The desired pressure and flow rate were achieved during normal operation of the system and during the LVAD test phase. Also, the fluid level sensor worked appropriately.

Many of the specifications for this trainer were meant. The heart is pressurized and is in the proper position in relation to other organs. The use of silicone as skin and choice of frame dimensions allow for the proper simulation of surgical field and confined workspace. Even specifications for matching an average patient, such as thoracic cavity volume and body surface area were met.

There were a few specification areas in which the specifications were only partially achieved. For example, the specification area of quick setup and teardown required a 30 minute initial preparation time, 15 minute between uses preparation time, 1 hour teardown time, and both one power cord and one power switch. Due to a lack of availability of a pig or calf heart, the setup and teardown times were not able to be verified. The use of one power cord was achieved (the only power cord needed to be used by the surgeons is the one powering the iso-transformer). However, the surgeons will need to work with two power switches, one for the iso-transformer and one for the laptop.

There were also a few specifications that just could not be met. The specification for the heart beat rate was not achieved. However, the customer gave permission to not pursue a beating heart for this first generation of this project. The amount of fluid in the system specification was also not met. It was desired to have approximately 5.6 liters of fluid in the system to simulate how much blood is in an average patient. However, the container found and used as the fluid reservoir for this first generation of the project can only hold 4 liters.

CONCLUSIONS AND RECOMMENDATIONS

It was desired to design an LVAD implantation simulator to allow surgeons a training opportunity for this surgery. The trainer was to match an average patient in terms of dimensions, and simulate the average surgery environment the doctor would face, to the best of the teams ability. The proposed trainer achieves most specifications given, including providing a realistic surgical field.

It is suggested that this project becomes a generational project. In the second generation of the project, the few specifications missed can be achieved. The trainer can also be updated to allow for the heart to beat. Improving the solutions to meet the portability and ease of transport customer needs further could also be a focus of the next generation of this project. The two phases of the project together will allow for the entire customer needs to be met.

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