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Arterial Line Placement Simulator

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THE DEVELOPMENT OF A RADIAL ARTERIAL LINE PLACEMENT SIMULATOR

A BIOMEDICAL ENGINEERING MAJOR QUALIFYING PROJECT SUBMITTED TO THE FACULTY OF WORCESTER POLYTECHNIC INSTITUTE FOR THE DEGREE OF BACHELOR OF SCIENCE

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Contents

Acknowledgements

This MQP project has implements many multidisciplinary facets of engineering that goes beyond mechanical and biomedical engineering. The efforts presented wouldn't have been possible without the guidance of my professors: Prof. Gaudette and Prof. Farber and Lisa Wall of the BME department, Prof. Savilonis and Prof. Blandino of the Mechanical department, and Russell Lang of the Civil Engineering department.

Many thanks to the faculty at UMMS for providing us the opportunity to work on this project. I owe my greatest thanks to Melinda Taylor of the UMMS simulation center and Akhter Mohammed, MD for inviting us to the facility and learn more about the simulation and medical fields.

Abstract

Currently, there are many medical simulators that provide a means to train operators on various medical procedures like arterial or venous access, patient care, or simply anatomical models. There are many factors that determine the efficacy of a particular medical simulator in teaching a medical procedure. This project reports the details in developing a medical simulator for teaching arterial access at radial artery. The objective of this project was to learn the aspects of creating a model feasible for teaching this procedure. A comprehensive study was conducted evaluating the kinematics, anatomy, and physiology of the human arm. A model was produced and presented to our clients. Medical practitioners will further validate this model.

Table of Figures

Table of Charts & Tables

1.   Introduction

What is the "Arterial Line Placement Simulator"?

      The arterial line placement procedure is a surgically invasive procedure of cannulating an arterial vessel for the measurement of the patient's vital signs during an extended operation, introduction of other devices into the arteries, and performing heart surgeries. This surgical procedure requires practitioners to tap into a patient's artery usually by techniques that require numerous trials to perfect; therefore, therefore it is essential to reduce the incidence of errors. Today, trainees commonly perform this procedure on living patients with supervision of a doctor. Simulators are low-risk tools used to perfect a practitioner's skill with no risks of malpractice. There are many simulators that exist in the market used for this procedure especially on the femoral artery; however, the clients have requested for a realistic simulator used specifically to tap the arm's radial artery thusly titled an arterial line placement simulator.

      The proposal of developing a simulator is granted by the clients Melinda Taylor, a senior engineer, and Dr. Mohammed Akhter, cardiologist, both of the University of Massachusetts Medical School (UMMS). Glenn Gaudette, PhD, professor of the biomedical engineering department, and Brain Savilonis, PhD, professor of the mechanical engineering department, are both of WPI and are the advisors to this project. In all, this report is intended to inform the reader, and document all relevant processes in the development of an arterial line placement (ALP) simulator.

2.   Literature Review

2.1:   History

We always would like to know what a particular outcome will be when making decisions in order to minimize losses and seek gains. Simulators have long employed in many fields of study to determine real-world outcomes that don't carry its inherent consequences and therefore; giving the manipulators the opportunity to improve their strategy. By definition, a simulation is the imitation of an operation of a real-world process or system that runs over a period of time. A model is needed that closely relates to the real-world process, and the simulation is the operation of the model over time (Banks, Carson and Nelson).

Chess is an example of a simulation that was devised as a military simulation in the sixth century, and during the Renaissance period, the robot of Leonardo da Vinci was built for defense purposes (Rosheim) and medical simulations in its primitive form appeared as anatomic physical models before the rise of plastic and computers. It's not until recently that the pioneering of simulators for pilot and medical training in the early 20th century ensued. Edwin Link, the inventor of the first flight simulator, built and patented a prototype "blue box" for sakes for an easier, safer, and less expensive way to learn to fly (Rosen, 2008). During World War II, the military officers a saw and increase in pilot accidents due to poor visibility and purchased Link's trainers to improve pilot competence. The increasing demand of the simulators quickly established a business for Link Aviation where the military increased orders of the trainer. In 1955, the Federal Aviation Administration required simulation recertification to maintain commercial pilots' licenses. Many other events over the course of the 20th century have raised the simulator's potential to illuminate problematic situations. A few notable cases where simulations have proved their worth were during Apollo 13 and Skylab 2 repairs among others.

The military was the driving force in raising the medical industry to the benefits of simulations - 80% of all simulation production prior the 1990s. Since then, the gaming industry has taken the lead in the development of computer-based simulations with its particular focus on high-resolution graphics. The integration of the rudimentary methods of simulation yielded the first medical simulation: Rescusi Annie, which was developed by Laerdal in 1960 for the practice of the cardiopulmonary resuscitation. Significant advances weren't realized until the 1990s where four factors are said to have contributed to the design of advanced task training

systems: the Visible Human Project, minimally invasive surgical techniques, haptic systems and the computer.

These vast efforts over the course of simulation development lay a path to a promising field in more realistic models, yet there still are many obstacles that have yet to make this technology widely accepted in medical education. Validity of the education from simulator training is still widely contested and is mainly attributed to its delay in implementation. However, there has been growing acceptance for medical simulators as the costs of equipment, programs and personnel have been offset by the collaboration of simulation centers and preference by specialists as a competency requirement during residency and licensure.

2.2:   Validity of Simulator-Based Training

A quick thought in designing and producing a mechanism that can replicate the complex functions of the human body appears daunting – the prescription of functions of the simulation while being within budget assigned. Project constraints for replicating a bodily part and function may be too limiting to be of any benefit for the practitioner or in the worst case, the skills learned may mislead the student which could result in malpractice and incur heavy costs for the institution, manufacturer. Simulations in aviation history have proven to be very effective, however the complexity of the human body has left the medical industry with limited resources for practicing medical skills like living animals, and cadavers.

The recent advent of medical simulations has raised the issue whether these present models are effective in medical training. The value or validity of medical simulation education has been minimally tested in the medical field, and as quoted by David Gaba, "No industry in which human lives depend on the skilled performance of responsible operators has waited for the unequivocal proof of the benefit of simulation before embracing it (Rosen M.D.)".

Many educators have attempted to document the benefits of medical simulation. The efficiency of the medical simulation is based on its capacity to produce objective measurements and skills acquired by the operator. The key to error prevention is not so much the detection of error or paired complications, but the detection of near misses and the prevention of related errors and complications (Fried, Satava and Weghorst). This ultimately implies that there needs to be a feedback system implemented in the medical simulator and a complementary user interface to relay these measurements. Endoscopic simulator procedures use a robotic interface device and transmit force feedback to provide the trainee with tactile sensations (haptic

feedback) that mimic the feel of the actual procedure (Kincaid and Westerlund). It's still unclear whether high-end medical simulators can be justified as an appropriate method for improving the operator's skill. Laparoscopic trainers have been shown to be an effective training method for the acquisition of skills. Even though it is reported though that the training transfer from simulated environment may only be 25% (Rosen M.D.), the results in a study conducted in the department of medical education at the University of Michigan Medical School, show evidence that supports simulation-based training for placement of vascular access devices improve clinical performance (Andreatta, Chen and Marsh).

In conclusion, there is an elevated support of the medical simulators in skill training and maintenance. Although a high degree of sophistication is needed to fully replicate the human body, and provide feedback for near faults, more development in medical simulators is required. As in the case of an Institute of Medicine report: if one Boeing 747 crashes and kills 450 passengers it makes national headlines; however, if over 200 were to crash in a year, equal to the number of patients that die in hospitals each year as a result of medical human-error accidents, Americans would demand change (Kincaid and Westerlund)". The least that this project can achieve is to stir the development of medical simulations to effectively teach trainees on the respective medical procedures.

2.3: About Arterial Line Placements

Our clients requested for us to create a radial ALP simulator that would be able to replicate the physiological and anatomical features of a human arm as possible while being within project objective and constraints, mainly for reason that they were in a need for a simulation that would function as laboratory model to train medical students and other resident practitioners. Throughout our literature review session we uncovered that the market is mainly saturated with full-body mannequins or femoral line placement simulators. The very few of radial arm simulations were functionally modest as compared to the full-body or femoral line simulators as displayed in the benchmarking section.

Table 1: Common sites for Arterial Line Placement

Cannulation site	Advantage	Disadvantage

Radial Artery	Easy access, Does not limit patient mobility	May be too thin or pulse may be absent, Circulation may be poor through the ulnar artery
Brachial/Axillary Artery	Large Artery, Pressure correlate closely with aortic pressures	Thrombosis may cause reduced flow downstream in the arm, Restricts mobility at the elbow
Femoral Artery	Large artery, Pressure correlates closely with aortic pressures	Thrombosis may cause reduced flow downstream in the leg, Restricts mobility at the hip

The common indications for the arterial line placement procedure include the measurement of arterial blood pressure, frequent estimation of arterial blood gasses or other blood chemistry is necessary. Contra-indications: sepsis, peripheral vascular disease, coagulopathy, thromboangiitis obliterans and Raynaud's phenomenon (Society).

There are two methods of performing the arterial line placement ALP procedure, the cannula-over-needle technique, and the Seldinger's procedure. Prior to performing the ALP procedure, patient or medical proxy consent is required and noted, the Allen's test, which tests for the blood patency, and flushing of the arterial line tubing with normal saline (to reduce the risk of air embolism) is needed.

This is an example of the ALP placement procedure per the Internal Medicine Residency Program at the University of Minnesota (Kohlman). The following materials are necessary to perform the arterial line placement procedure.

- Arterial line insertion kit,
- Chloraprep swabs,
- Disposable chucks,
- Arterial line monitoring equipment,
- Ultrasound Site-Rite™ with sterile drape kit (if necessary),

- Pulse doppler (if necessary).

1. Restrain the wrist over a rolled towel in dorsiflexion and the palm oriented upwards. Make sure the blood pressure cuff is in placed on the contralateral arm as not to impede blood flow while placing the line.
2. Sterilize (per proper aseptic technique) and adequately anesthetize the puncture site.
3. Hold an 18 or 20 gauge needle like a pencil and puncture the skin at a 30° angle. To feel the radial pulse, use your index finger by starting medially and move laterally.
   a. If the radial pulse still can't be felt, consider using ultrasound or Doppler to visualize the artery.
4. Advance needle until a flash of blood is observed, then slowly advance the catheter while removing the cannula.
   a. There are two catheters in an arterial line kit; use the longer one if possible.
   b. Seldinger's technique may be used if this feels more comfortable.
5. Once the catheter is placed, hook the flushed arterial line transducer tubing to the catheter tip. Evaluate the waveform to ensure accurate reading.
6. Secure the line to the skin with the provided suture.

The most common difficulty with ALP is arterial spasms, which often hinders the clinician to pass the guide wire through the artery. At times, the guide wire cannot be passed despite the flash of blood and may be because of the angle at which it was inserted in relation to the artery was too acute or because the needle is not completely in the artery (Tegtmeyer, Brady and Susanna). The adjustment of the angle entrance of the placement may prove to be successful.

2.4:   Benchmarking

Necessary to every design development, a comprehensive inquiry is needed to better understand the necessary processes of manufacturing such simulators, avoiding intellectual infringement, or worse yet, reinventing the wheel. Benchmarking illuminates the capabilities of products or published works and confidence during the initial development process. The team had devoted some time to peruse leading simulator companies for products that meet or nearly

fulfill our project objectives. The descriptions list information that might be useful for giving insight for market competition. Below is a list of contending simulators:

2.5.1: Marketed Models

Simulators

A. Product Name: Arterial Arm Stick (Arm Only), (PN# 375-80001)

    Company: Laerdal Medical Corporation

    Debut: N/A

    Laerdal Corp carries one simulation of the radial arm under the name Arterial Arm Stick Kit. It is described as a "lifelike adult male arm reproduction with infusible arteries designed for training the proper arterial puncture procedure for blood gas analysis". Among these this feature, it is able to simulate the hand placement during the Allen's Test, artery palpitation is possible, has two percutaneous puncture sites at the radial and brachial arteries, can be pressurized with the capacity for flashbacks. It is furnished with a replacement skin and artery set, 5 syringes, simulated blood, lubricant, carry case and directions for use (Laerdal Medical Corporation).

B. Product Name: S402 Arterial and Venous Patient Training Arm

    Company: Gaumard Scientific

    MSRP: $710.00

    Debut: N/A

    On a search on the Gaumard website, the arterial arm simulation can simulate pulsatile arterial blood flow, can perform AV anastomosis/hemodialysis, capable of having standard intravenous, infusion, and blood collection techniques performed on it, has intramuscular injection site in the deltoid area, subcutaneous injection areas on the volar side of the forearm and lateral side of the arm, has a venous network in the arm and hand, connects to all Gaumard adult simulators, uses a squeeze bulb to increase or decrease venous pressure among other features. Its veins can stand out or collapse, and realistic "pop" as the needle enters the vein, and the veins and outer skin have the capacity to reseal. It can simulate a clenched fist and tourniquet position (Gaumard(R) Scientific).

C. Product Name: FemoraLineMan System, (PN#FLM-30)

    Company: SimuLab Corporation

MSRP: $1,230.00

Debut: N/A

   The simulation responds to ultrasound, has realistic soft tissue, includes all necessary anatomical landmarks, includes palpable arterial pulse present to avoid and detect errors, has two colors of simulated blood, easy to refill simulated fluid reservoirs, portable and affordable, differentiates arterial and venous blood to show positive or negative results, self-sealing veins and skin for multiple practices, replaceable tissue sets allow for multiple uses.

Pumps

A. Product Name: Series 1400 Pulsatile Blood Pump

  Company: Harvard Apparatus

  Debut: N/A

Figure 1: The 1400 Series of the Harvard Apparatus Pulsatile Pump: Image Courtesy of Harvard Apparatus

  Description: There are four models of the Harvard Pumps all using the same design though each designed to accommodate for varying animal body sizes – rabbits, mice/rats, or dogs/monkeys or and other large animals. It is a piston pump that assures that all blood is emptied from the cylinder at every stroke. Valve cages and liquid pathways are designed to provide a streamlined flow with no sharp edges to minimize hemolysis, and also for easy disassembly for cleaning and sterilization. Another noteworthy feature is the capability to alter the stroke volume during pump operation and, the electronically variable ratios of the systole (larger pumps) (Harvard Apparatus).

B. Product Name: AccuFlow-Q Doppler Physiological Flow System

    Company: Shelly Medical Imaging Technologies

    Debut: N/A

Figure 2: Accuflow-Q Doppler Physiological Flow System: Image Courtesy of Shelly Medical Imaging Technologies

Description: AccuFlow-Q is a flow pump system designed to generate realistic physiological volume flow waveforms. It is also capable of appropriating flow systems in tissue phantoms by ultrasound systems. It uses a high performance micro-stepping motor coupled with custom designed motor controller. This is the cheapest peristaltic pump model Shelly Medical Imaging Technologies has developed and marketed (Shelly Medical Imaging Technologies).

2.5.2: Patents

Several patents have been filed and posted on the topic of simulators and physiological pumps.

A. US Patent: #5,215,469

    Title: <u>Training Apparatus for the Practice of Puncturing Blood Vessels</u>

The claims reported by this patent include an airtight, liquid-tight compressible liquid container (19) with a two-way pressure threshold valve for transferring liquid between the container and the arm. It also includes a tight-fitting cover (32) that resembles the mechanical properties of skin and at least one puncturable tube (31) connected to the liquid container and laid between the skin and the arm core (14) (Køhnke and Petersen).
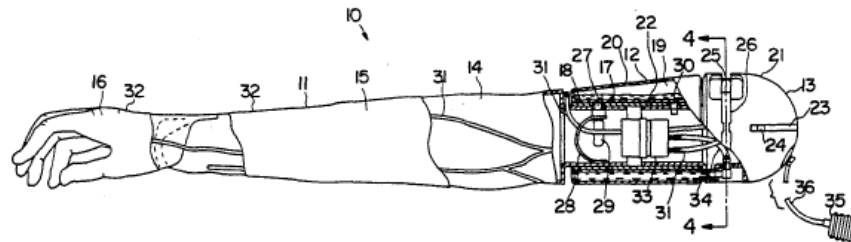
Figure 3: A sketch of the training apparatus cannulation arm.

B. US Patent: #3,784,323

Title: <u>Peristaltic Pump</u>
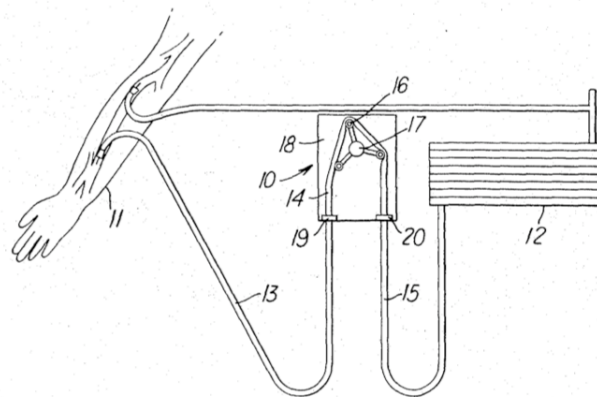
Figure 4: Figure of a Peristaltic Pump.

The claims supported in this publication are the methods of using three cylinders and compressible silicone elastomer tubing to displace fluid within the tubing, and the operation of adjusting the compression rollers equidistant to each other and moving the pumping source longitudinally of the reservoir (Sausse).

C. US Patent Pub #: US2006/0008786A1

Title: <u>Vascular-Access Simulation System with Three-Dimensional Modeling</u>

Claims: Uses haptic feedback systems to signify the placement and point of cannula insertion (Feygin, Higgins and Ho).
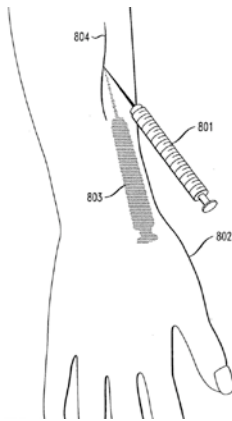
Figure 5: Haptic Feedback Vascular-Access Simulation
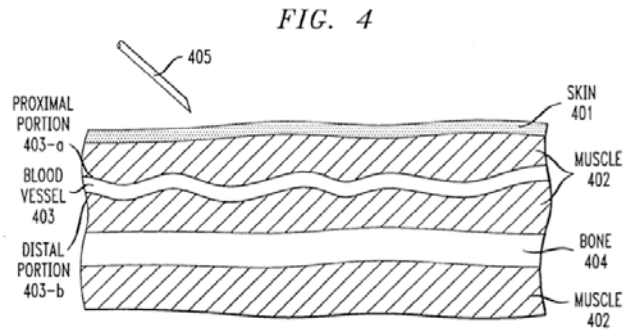
D. US Patent Pub #: US 2011/0200977A1

    Title: Cannulation Simulator

The claims reported in this patent are that the cannulation zone comprises of a layer of clear, gelatinous material that would have similar mechanical properties that approximate human loose connective tissue. A silicone tube would simulate a vein situated within the polymeric gel material. An elastic polymeric film would cover the polymeric gel layer on the surface of the cannulation field (Paronen).
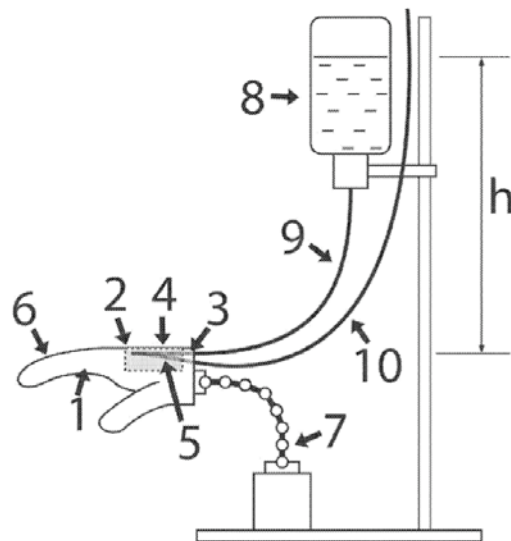
Figure 6: Cannulation Simulator

3.   Project Management

Essential to this project's efficiency are the implementation of useful project management tools need to control the design process. We use RefWorks to gather and document literature review sources. Wimba may be used as a remote conference meeting software tool used to contact our clients in the effort to reduce costs. Microsoft Office is used to word process, manage budgets, send email, timelines, schedule meetings, communicate processes, and manage data. (Word, Excel, Presentation, Outlook, Project are used). More tools may be implemented or discontinued over the course of the project.

4.   Design Definition

4.1.   Client's Problem Definition

Initial Client's Objective Problem Statement:

"Monitoring patients can sometimes include access to arterial blood. This is usually accomplished through the placement of an arterial line in either the arm of leg of a patient. There currently exists a need for an improved arterial line placement simulator. This project will design a model (and build prototype) to simulation arterial line insertion. It should incorporate pulsatile flow, be anatomically correct, and simulate the human arm in regards to the biomechanical response of skin, muscle and blood vessels."

Revised Initial Client's Objective Problem Statement:

"Design a realistic model and develop a prototype that is used to simulate the insertion of an arterial line. The model should incorporate pulsatile flow, be anatomically correct and simulate the biomechanical response of skin, muscle and blood vessels."

Final Client's Objective Problem Statement:

"Design an anatomically and physiologically realistic and functional model of a radial arm simulator and develop a prototype that is used to simulate the insertion of an arterial line through the radial artery. The anatomically and physiologically realistic and functional model of the radial arm should, at the least meet the following: provide a pulsatile flow through the radial artery and demonstrate a realistic flashback upon cannulation."

4.2.   Project Objectives

This section comprises three topics that were discussed and evaluated between us, clients and designers, in order to establish a common understanding of the amount of collaboration needed throughout the project and expected deliverables. Those topics are the pairwise comparison chart, the project objectives, and the project constraints.

4.2.1. Objectives

As designers, we suggested to our clients the possible functions the simulator could perform based on the skills we had (since this project wasn't assigned per level of designer competence, but merely our preference for it) and therefore a heuristic team evaluation would be uncontested and reasonable to establish the objectives needed to be met in designing the RALP and likewise, our client's voiced ideas that we need to be aware of from their experience in these procedures. Altogether, there are four main objectives established for the project's success and, are organized in a hierarchical format. Lesser objectives are defined below greater objectives, and will have designated levels of priority as discussed in section 4.2.2.

The (S) objectives relate to the simulator; (P) objectives relate to the pump.

1) It should be functional and operable. (S,P)
    a) It should be realistic. (S,P)
        i) It should exhibit a healthy patient's anatomical and physiological properties. (S)
            - It should have the same anatomical features from the fingers to the part below the elbow including articulations and eminences. (S)
            - It should display realistic circulatory response including an automated, and adjustable pulsatile flow. (P)
            - It should respond realistically to cannulation; it should exhibit flashback and emit a "pop" sound. (S)
    b) It should be compatible with common laboratory and other interfacing equipment. (S,P)
2) It should be user-friendly. (S.P)
    a) It should be safe. (S,P)
        i) It should be designed with hypo-allergenic materials. (S)
        ii) Moving parts should be concealed and electrical leads insulated. (P)
        iii) It should have an emergency kill-switch. (P)
    b) It should be easy to wield. (S,P)
        i) It should have easily replaceable parts. (S,P)
        ii) It should be portable. (S,P)
        iii) It should require the least amount of operators. (S,P)
        iv) It should be easy to maintain. (S,P)
        v) It should function automatically. (P)

3) It should be durable. (S,P)

4) It should be marketable. (S,P)

    a) It should be manufacturable on a small-scale. (S,P)

    b) The resources used should be reliably inexpensive and available.

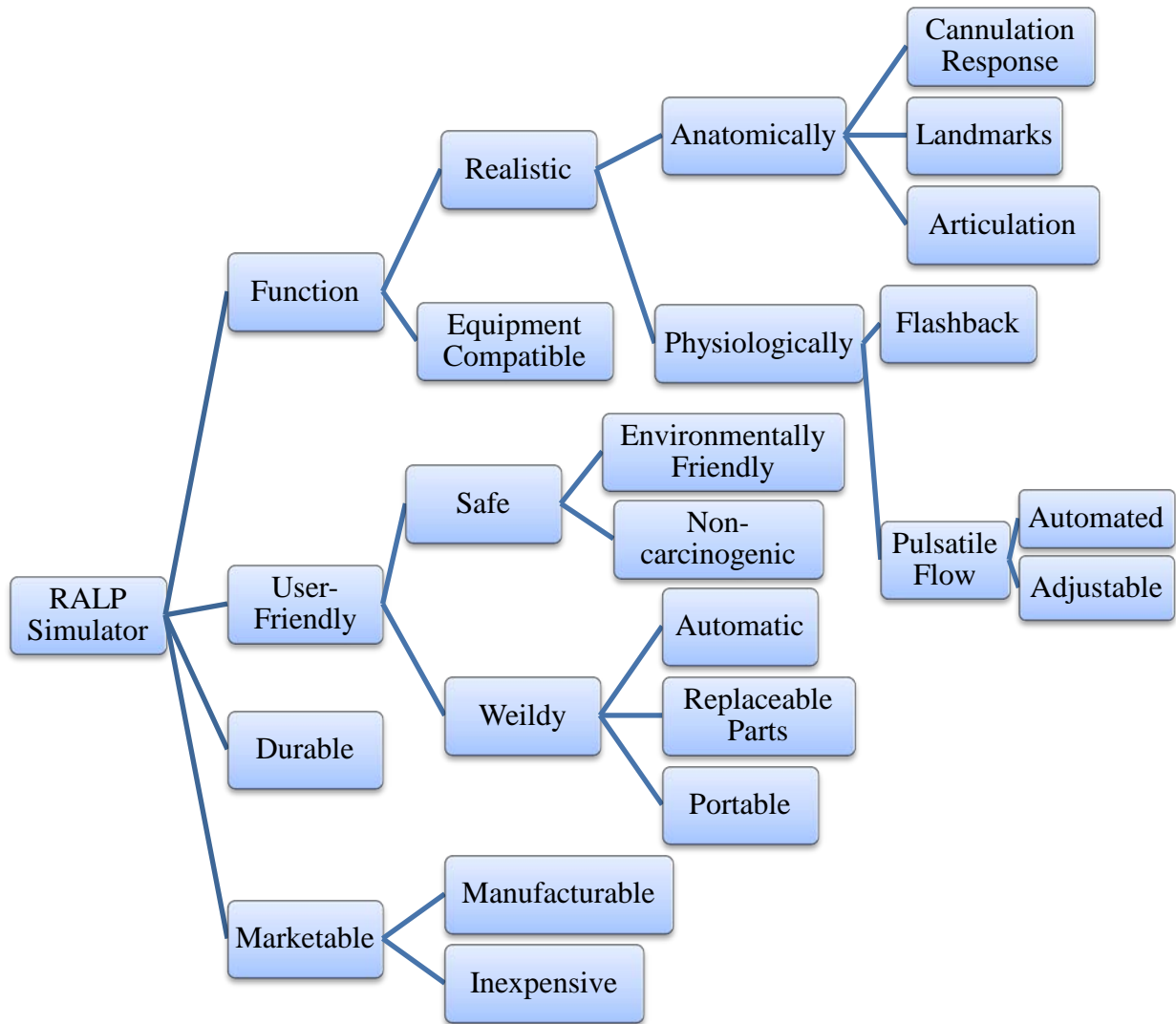*Figure 7: Objective Tree for the Arterial Line Insertion Simulator.*

4.2.2. Pairwise Comparison Chart

The use of the pairwise comparison chart (PCC) is a quintessential tool to assign priority to an objective. There can be many objectives to consider in the definition of a design object, and that depends on the present or working, cognizant knowledge of the members involved in the design

process. A significant amount of knowledge is gathered during the literature review sessions, though there is certainly some learned during the other processes of the project like the realization and verification processes. This can be an iterative procedure though no more resources need to be spent based on what is budgeted for the entire project. Enter the pairwise comparison chart (PCC). The PCC is used to align objectives in priority by the client's request. It performed based as a logical contest between the entries in the "GOALS" row versus those in the "GOALS" column. A contested objective with a higher priority or preference is assigned a "1" over the lesser, which receives a "0". A tally is summed in the "TOTAL"'s column and, thus the objective priority list is established. When using this method the opposite side is a reflection with opposite values. *Table 2* below shows the chart completed in one of our meetings.

Table 2: Objective Pairwise Comparison Chart

GOALS	Function	User-Friendly	Durable	Marketable	TOTAL
Function	XXX	1	1	1	3
User-Friendly	0	XXX	0	1	1
Durable	0	1	XXX	1	2
Marketable	0	0	0	XXX	0

4.2.3. Project Constraints

This year, students working on an MQP project are reimbursed a maximum $156.00 by the Biomedical Department with a valid receipt of purchase. All other costs will be handled by the student. The scheduled date for the delivery is April 1, 2011. There are other constraints that would be strictly important if this project were to be carried forth past this stage, those being the WPI's, UMMS, and other governmental regulations on safety, manufacturing, and testing. It is necessary to be aware and implement a basic manufacturing ethic in the development in of the radial ALP.

4.3. Establishing Functions

In order to meet client objectives, there needs to be a quantified and defined boundary to which each component of the simulation shall accomplish. To determine the limits of what the

RALP could do, the function-means tree exercise was performed to evaluate its functional possibilities and methodological possibilities.
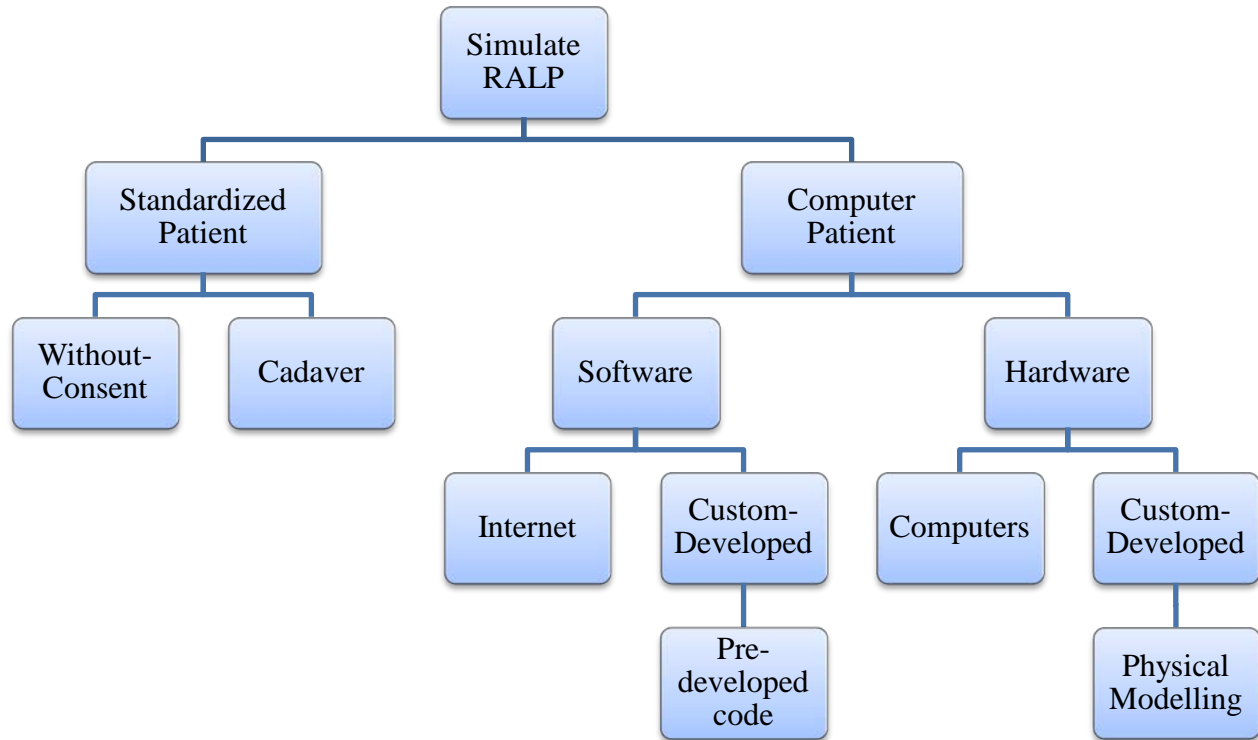
Figure 8: Function-Means Tree

4.4. Design Specifications

As discussed in the Validity of Simulator-Based Training section, constructing human arm features and functions exactly in a simulator is infinitely complicated and very ambitious leaving this project as a paradox. Specifications are universal standards agreed upon by the involved organizations to assure a product, service or procedure meets the specified quality, usually denoting the use of weights and calibration. This project's specifications are set by our clients to ensure expected deliverables and limit the design landscape. The designs' specifications are organized as addendums of the objectives. For most technical work, numbers are used to determine specifications, often with careful attention to the tools used to define those figures. Calibrations and weights are employed, however, the caliber of this work requires minimal attention to numerical specifications, but acute qualitative specifications are demanded.

As this is not a prototype of any simulator scheduled for production or general public use, numerical specifications are kept to a minimum.

1) *Functionality and Operability (S,P)*

    a) *Realism (S)*

        i) *It should exhibit a healthy patient's anatomical and physiological properties. (S)*

- *It should have the same anatomical features from the fingers to the part below the elbow including articulations and eminences. (S)*

The radial artery is required to be present on the RALPS, which is to be situated at the correct site necessary for the palpation of the radial pressure point. It should accommodate a gauge cannula of 18-22.

- *It should display realistic circulatory response including an automated, and adjustable pulsatile flow. (P)*

The circulatory response in statement is the palpable radial pressure point. It needs to be similar to a healthy patient.

- *It should respond realistically to cannulation; it should exhibit flashback and emit a "pop" sound. (S)*

The radial artery is required to show blood flashback with the correct amount of flow.

    b) *It should be compatible with common laboratory equipment.*

2) *Usability (S.P)*

    a) *It should be safe. (S,P)*

        i) *It should be designed with hypo-allergenic materials. (S)*

There are many materials that may elicit an allergenic reaction in many people. Avoid the use of latex if possible.

        ii) *Moving parts should be concealed and electrical leads insulated. (P)*

        iii) *It should have an emergency kill-switch. (P)*

    b) *It should be easy to wield. (S,P)*

The arm which will be replicated will be right hand.

        i) *It should have easily replaceable parts. (S,P)*

        ii) *It should be portable. (S,P)*

iii) It should require the least amount of operators. (S,P)

The RALP requires no more than one person to operate.

iv) It should be easy to maintain. (S,P)

v) It should function automatically. (P)

3) *Durability (S,P)*

4) *Marketability (S,P)*

a) *It should be manufacturable on a small-scale.(S,P)*

b) *The resources used should be reliably inexpensive and available.(S,P)*

4.5.   Preliminary Designs

Arm Designs:

1.   Mannequin Mold

The mannequin cast is very similar to the common marketed designs where the mold itself has grooves/channels on its exterior where the blood vessel can be laid. Wood carved out to resemble the radius and ulna with an articulating wrist would be situated in the cast. Copper tubing (CT) would be formed to give structure to fingers. A retractable cord would give the spring action of the palm portion of the bone and the forearm bone.
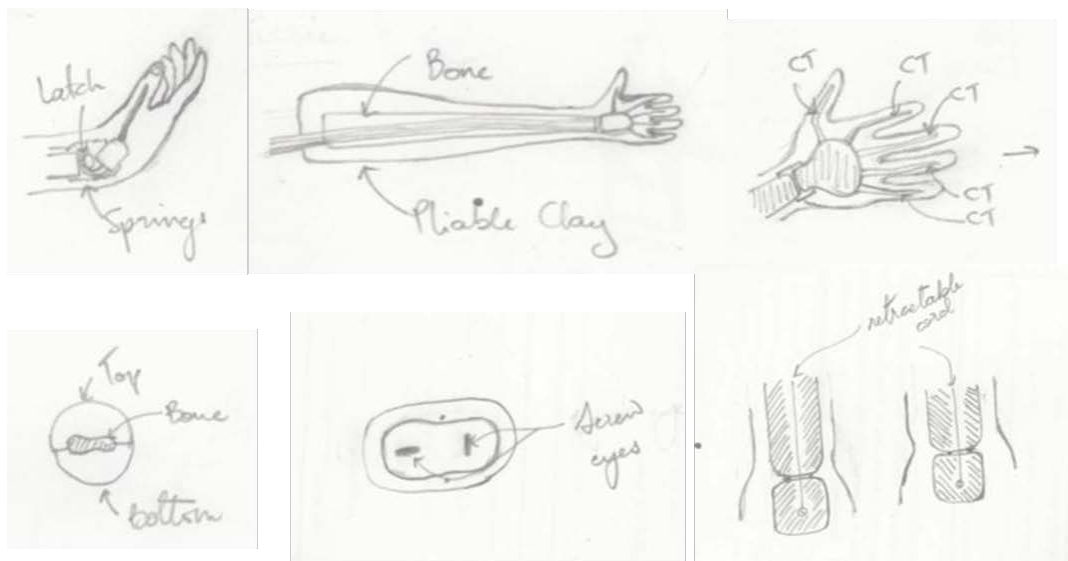
Figure 9: Compilation of the forearm sketches.

Pump Designs:

1.   Squeeze Pump

Marketed RALPSs or intravenous simulators use the squeeze bladder pump to actuate fluid through the vessels. There are check valves that restrict back flow, and only when all fluid is out of the baster, does the fluid upstream refill the baster container.

Figure 10: Squeeze-bulb sketch

2.   Diaphragm Pump

As the name implies, the diaphragm pump uses the benefit of an elastic portion of the volute to change the internal volume.
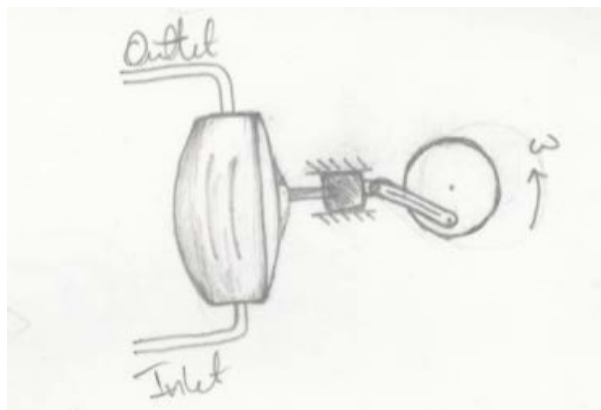
Figure 11: Diaphragm Pump

3.   Off-phase Peristaltic Pump

A casual search for pumps used in the medical field will reveal the peristaltic pump, almost exclusively, and with each, different specifications and recommended uses ar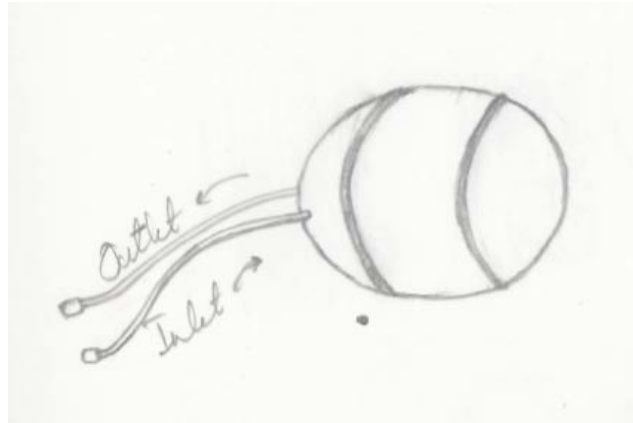e paired. Its fundamental design is simple, and relatively simple to manufacture as shown in (our figures below). The only deterring factor not to obtain a marketed pump was its expensive price.
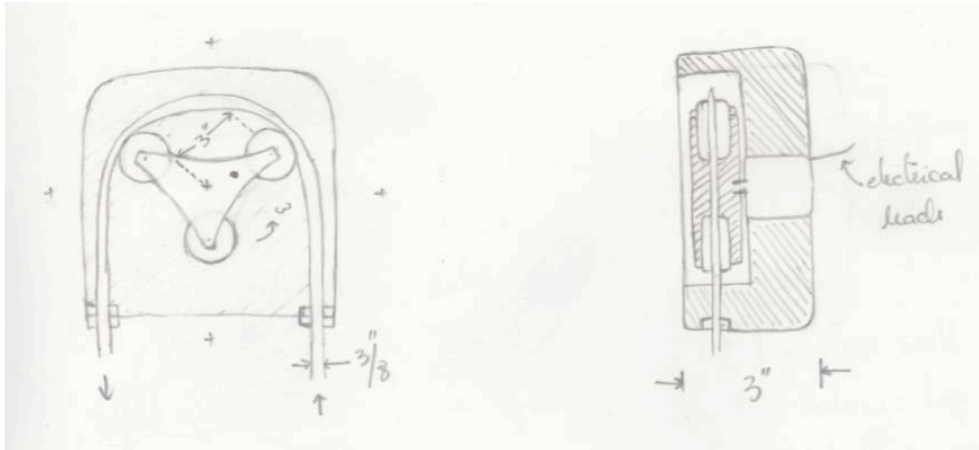
Figure 12: Off-phase peristaltic pump

4. Piston Pump
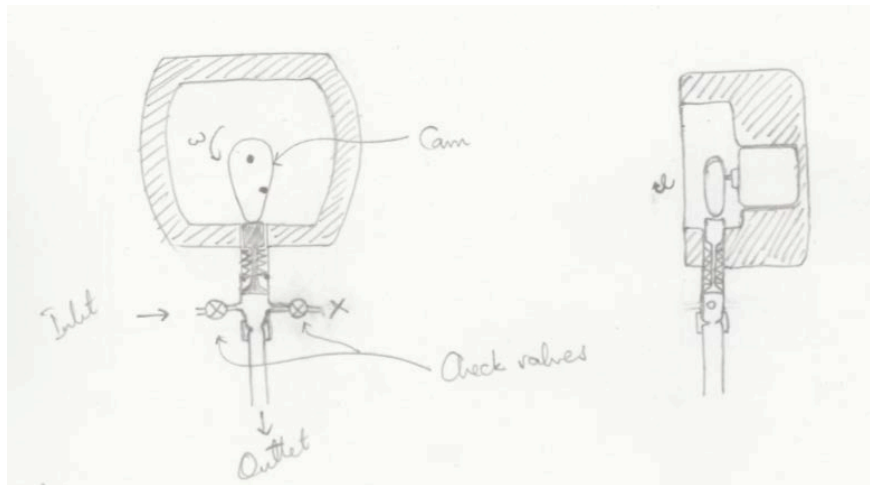
Figure 13: Piston Pump

Regulating devices would either be upon the basis of controlling the speed of the pump by pressure reduction created upstream or by the level of the blood in a tank interposed between the patient and the patient and the pump. These devices are delicate and bulky and have not found general application.

To determine the reliability of certain components of the entire model, simple concepts were tested individually to ascertain its function before its entire assembly.

4.6.   Final Conceptual Design

After exploring the individual components of the RALP, an organization of connections and direct interactions fully lays out the design plan as illustrated in *Figure 9*.
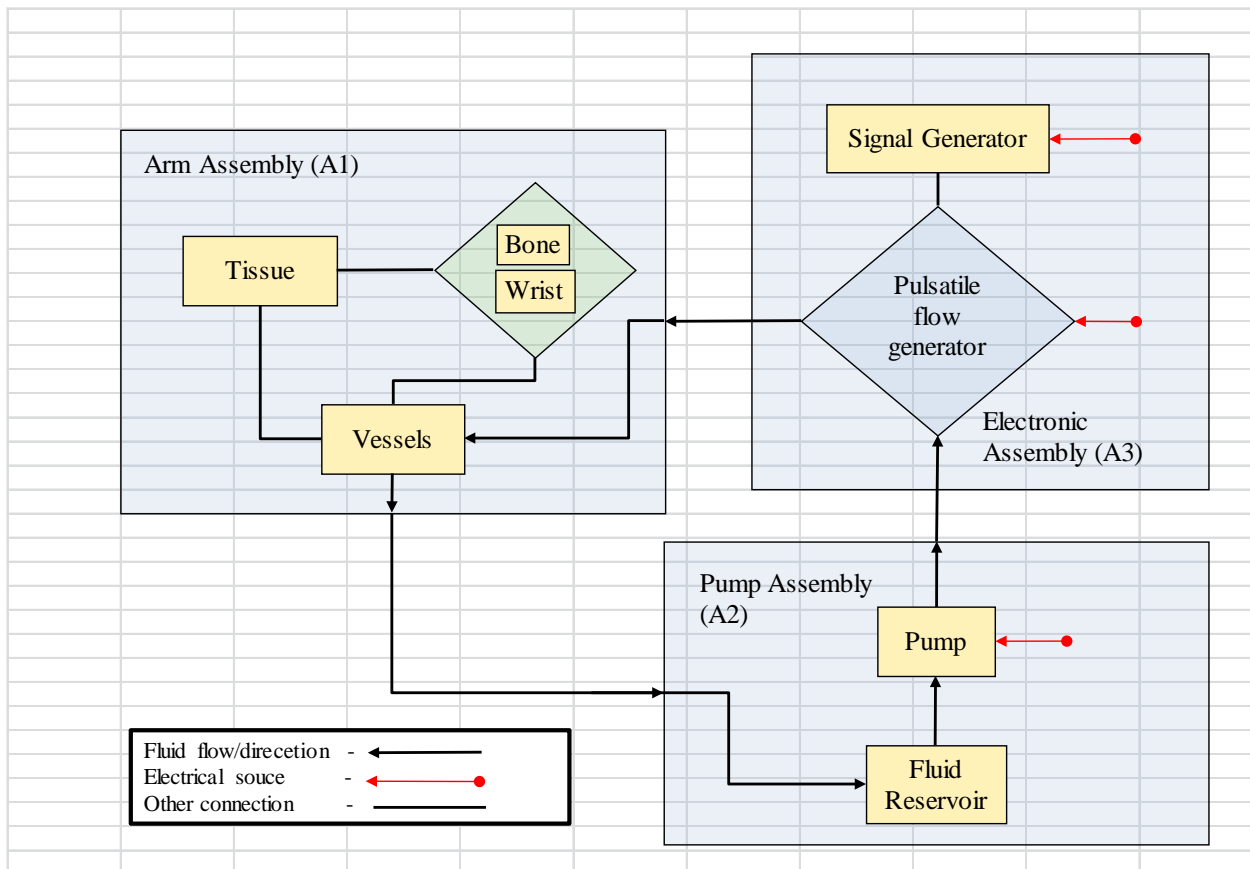
Figure 14: A schematic of the ALP simulation components and assemblies

5.   Design Verification

Arm Assembly (A1)

The four main components of the arm assembly much like the human arm constitute of the bones, tissue, blood vessels, and the skin. There is a blood component that is also part of the arm assembly however; this component will be investigated as part of the entire assembly (A1).

Designer's Evaluation: As depicted in the final conceptual design, the bone is designed to hold the tissues well when A1 is assembled. The following process will determine the structural integrity of the arm assembly when dropped from a certain height (here assigned 1 meter) to provide a range of forces that A1 can still be functional, in essence, to simulate the condition if the simulator were to drop from a work bench. We will investigate the mean acceleration experienced when the simulation is dropped from table height (<1.5m). A factor of safety calculation will be performed to specify a range of forces where the simulation may still be functional. A second evaluation (or singular) of cannulation sound will need to be conducted to evaluate real-life cannulation simulation.

The assembly will be treated as an monetary asset and, to maintain its initial cosmetic shape for future use, the critical velocity change shock test procedure indicated in (ASTM D3332-99) will be used to perform the following shock test.

Bone (A1-1)

Designer's Evaluation: --

Client's Evaluation: --

Test 1: Weigh A1-1

Calibration Procedure:

1. Zero the scale (if possible)

Experiment Procedure:

1. Place the A1-1 on the measuring scale.
2. Record A1-1's weight.

Report:

1. Report the type of material tested
2. Any Calculations
3. Manufacturer, part numbers, lot numbers for the needles.
4. Report A1-1's mass

Muscle Tissue (A1-2)

Designer's Evaluation: Measure the mass and material resistance to needle puncture.

Client's Evaluation: --

Materials List: Assembly A1-2, polychloroprene film, Trelleborg Coated Systems US, Inc, PN REEVES NS 5550; Measuring Scale: (to be specified); *Testing machine*: Instron (will be specified), DAQ system (will be specified); *thickness gauge* (able to measure up to 0.01mm); *hypodermic needle puncture probe*: 28 gauge hypodermic needle (will be specified); specimen support assembly: (will be specified with figures)

Test 1: Weigh A1-2's weight.

Test 2: Evaluate A1-2's resistance to puncture.

Calibration Procedure:

1. Create a specimen.
    a. Two square test specimens, 8.9 by 8.9 cm each shall be prepared. Cut holes through the specimen to accommodate support assembly fasteners.
2. Validate the lot of hypodermic needles:
    a. Identify manufacture's lot number
    b. Randomly select seven needles from the same manufacturing lot and conduct three puncture measurements on a specimen of A1-2 as explained in the experiment procedure below.
    c. Repeat 2.a-2.b for the second specimen.

d. If the needles within this lot fall within the range specified in the table below
(Table 3), they are valid for performing the experimental procedure. Otherwise,
the lot of needles cannot be used to acquire data in the experiment.

Table 3: Lot Validation Table for Hypodermic Needles

Needle Gauge	Avg. Peak Force Target (N)	Tolerance (±)	Standard Dev. (max)
28	0.822	0.189	0.105
25	1.134	0.17	0.115
21	1.538	0.251	0.158

Experiment Procedure:

1. *Measure the thickness of the exterior of A1-2 to the tip of the probe.*
2. Configure the specimen support assembly, and a specimen of A1-2.
   a. Secure the two specimen support plates to the testing machine using a
   machine interface plate. The needle and the specimen interface should be
   perpendicular to each other.
3. Place A1-2 probe 25mm beneath the probe and in direct path of the probe. Assure that
   the distance from contact is adequate so that the probe is travelling at a constant speed
   upon puncture.
4. *Measure the length of the extended needle of the probe.*
5. Initiate the puncturing probe toward the tubing until the probe has completely
   punctured the tubing and replace the specimen.
6. Repeat steps 2 – 5 twelve times.
   a. *Record the average pressure resistance of the A1-2 specimen.*

Report:

1. Report the type of material tested (thickness)
2. Any calculations

3. Manufacturer, part numbers, lot numbers for the needles, and length protruding from the clamp.

4. Maximum force required for each puncture to the nearest 0.01 N in 12 trials.

5. Calculate and report the average and standard deviation of puncture force required to penetrate the material.

6. Include copies of the stress strain curves with labeling.

Referenced Documents: ASTM F2878-10: Standard Test Method for Protective Clothing Material Resistance to Hypodermic Needle Puncture.

Skin Tissue (A1-3)

Designer's Evaluation: --

Client's Evaluation: --

Materials List: Assembly A1-3, polychloroprene film, Trelleborg Coated Systems US, Inc, PN REEVES NS 5550; Measuring Scale: (to be specified); *Testing machine*: Instron (will be specified), DAQ system (will be specified); *thickness gauge* (able to measure up to 0.01mm); *hypodermic needle puncture probe*: 28 gauge hypodermic needle (will be specified); specimen support assembly: (will be specified with figures)

Test 1: Weigh A1-3's weight.

Calibration Procedure:

1. Zero the scale (if possible)

Experiment Procedure:

1. Place the A1-3 on the measuring scale.

2. Record A1-3's weight.

Report:

1. Report the type of material tested

2. Any Calculations

3. Manufacturer, part numbers, lot numbers for the needles.

4. Report A1-3's mass

Test 2: Evaluate tissue's resistance to puncture.

Calibration Procedure:

1. Create a specimen.
   a. Two square test specimens, 8.9 by 8.9 cm each shall be prepared. Cut holes through the specimen to accommodate support assembly fasteners.
2. Validate the lot of hypodermic needles:
   a. Identify manufacture's lot number
   b. Randomly select seven needles from the same manufacturing lot and conduct three puncture measurements on a specimen of A1-3 as explained in the experiment procedure below.
   c. Repeat 2.a-2.b for the second specimen.
   d. If the needles within this lot fall within the range specified in (Table 3), they are valid for performing the experimental procedure. Otherwise, the lot of needles cannot be used to acquire data in the experiment.

Experiment Procedure:

1. *Measure the thickness of the exterior of A1-3 to the tip of the probe.*
2. Configure the specimen support assembly, and a specimen of A1-3.
   a. Secure the two specimen support plates to the testing machine using a machine interface plate. The needle and the specimen interface should be perpendicular to each other.
3. Place A1-3 probe 25mm beneath the probe and in direct path of the probe. Assure that the distance from contact is adequate so that the probe is travelling at a constant speed upon puncture.
4. Measure the length of the extended needle of the probe.

5. Initiate the puncturing probe toward the tubing until the probe has completely punctured the tubing and replace the specimen.
6. Repeat steps 2 – 5 twelve times.
    a. Record the average pressure resistance upon the cannulation of the A1-3 specimen.

Report:

1. Report the type of material tested (thickness)
2. Any calculations
3. Manufacturer, part numbers, lot numbers for the needles, and length protruding from the clamp.
4. Maximum force required for each puncture to the nearest 0.01 N in 12 trials.
5. Calculate and report the average and standard deviation of puncture force required to penetrate the material.
6. Include copies of the stress strain curves with labeling.

Referenced Documents: ASTM F2878-10: Standard Test Method for Protective Clothing Material Resistance to Hypodermic Needle Puncture.

Blood Vessels (A1-4)

Designer's Evaluation: The designer assumes that the tubing will be penetrated through one vessel wall and any mechanical properties of the tubing will be negligible when oriented in its cylindrical form.

Client's Evaluation: --

Materials List: Assembly A1-4, polychloroprene film, Trelleborg Coated Systems US, Inc, PN REEVES NS 5550; Measuring Scale: (to be specified); *Testing machine*: Instron (will be specified), DAQ system (will be specified); *thickness gauge* (able to measure up to 0.01mm); *hypodermic needle puncture probe*: 28 gauge hypodermic needle (will be specified); specimen support assembly: (will be specified with figures); microphone (will be specified); *microphone* (a 13mm random-incidence condenser microphone recommended), acoustic calibrator.

Test 1: Weigh A1-4's weight.

Test 2: Evaluate tissue's resistance to puncture.

Calibration Procedure:

1. Create a specimen.
   a. Two square test specimens, 8.9 by 8.9 cm each shall be prepared. Cut holes through the specimen to accommodate support assembly fasteners.
2. Validate the lot of hypodermic needles:
   a. Identify manufacture's lot number
   b. Randomly select seven needles from the same manufacturing lot and conduct three puncture measurements on a specimen of A1-4 as explained in the experiment procedure below.
   c. Repeat 2.a-2.b for the second specimen.
   d. If the needles within this lot fall within the range specified in Table 3, they are valid for performing the experimental procedure. Otherwise, the lot of needles cannot be used to acquire data in the experiment.

Experiment Procedure:

1. *Measure the thickness of the exterior of A1-4 to the tip of the probe.*
2. Configure the specimen support assembly, and a specimen of A1-4.
   a. Secure the two specimen support plates to the testing machine using a machine interface plate. The needle and the specimen interface should be perpendicular to each other.
3. Place A1-4 probe 25mm beneath the probe and in direct path of the probe. Assure that the distance from contact is adequate so that the probe is travelling at a constant speed upon puncture.
4. Measure the length of the extended needle of the probe.
5. Initiate the puncturing probe toward the tubing until the probe has completely punctured the tubing and replace the specimen.

6. Repeat steps 2 – 5 twelve times.

    a. Record the average pressure resistance upon the cannulation of the A1-4 specimen.

Test 3: Evaluate sound created by the vessel during cannulation.

Calibration Procedure:

1. Place the microphone 0.1m away from the acoustic calibrator and make sure that all testing systems are operating.
2. Create a 5 second tone in one-third-octave bands specified in ANSI S1.11 from 100 to 5000 Hz.
3. Measure background noise in the laboratory.

    a. Follow steps 1 & 2 using the same microphone and analyzer gain settings as used for measurements of the receiving level. (Adjust the position of the acoustic calibrator at each tone unless the background level is more than 10 dB below the combination of signal and background. If the background level is between 6 and 10 dB below the combined level, correct the signal level using Equation 1.

Equation 1: Adjusting distance for ambient noise

$$L_a = 10\log[10^{\frac{L_{sb}}{10}} - 10^{\frac{L_b}{10}}]$$

L_b = background noise level, dB,

L_{sb} = level of signal and background combined, dB, and

L_a = adjusted signal level, dB

    b. Calculate for transmission loss at each frequency f from:

$$TL(f) = L_S(f) - L_R(f) + 10\log\frac{S}{A_R(f)}$$

Where:

TL(f) = transmission loss, dB,

L_S(f) = average sound pressure level in the source room, dB

L_R(f) = average sound pressure level in the receiving room, dB,

S = area of test specimen that is exposed in the laboratory, m^2, and

A_R(f) = sound absorption of the receiving room with the test specimen in place, m^2

Experiment Procedure:

(This procedure should be concurrent with Experiment Procedure of Test 2 of the Blood Vessel).

1. Initiate and set the microphone (to be defined) away from the puncture site.
2. Record any data received once Test 2 of the Blood Vessel is complete.

Report:

1. Report the type of material tested (thickness)
2. Manufacturer, part numbers, lot numbers for the needles, and length protruding from the clamp.
3. Date of procedure.
4. Table of all calculations, test conditions (humidity & temperature of the laboratory), and corresponding results.
5. Calculate and report the average and standard deviation of sound made during cannulation.

Referenced Documents:

1. ASNI E90-09: Standard Test Method for Laboratory Measurement of Airborne Sound Transmission Loss of Building Partitions and Elements
2. ANSI S1.11: Specification for Octave-Band and Fractional-Octave-band Analog and Digital Filters.
3. ASNI S1.10: Pressure Calibration of Laboratory Standard Pressure Microphones.

Pump Assembly

Designer's Evaluation: The pump is designed to generate a pulsatile flow similar to that of a human at the radial artery cannulation site.

Client's Evaluation: ---

Test 1: Measure the pump's volumetric flow rate.

Objective: Evaluate the flow rate.

Procedure:

1. Fill one beaker with water.
2. Place the receiving end of the tube into the water while the other end empties into an empty beaker.
3. Set the peristaltic pump to a selected flow rate.
4. Turn on the peristaltic pump on and simultaneously start the timer.
5. Stop the peristaltic pump and the timer simultaneously.
6. Record the time it takes to displace the water.

Report:

1. Data and analysis of the accuracy of the peristaltic pump.

6.   Design Realization

The procedures for the assembly of the arm, pump, and electronic assemblies are described below. Thereafter, further details to fit each of them together will be described.

6.1.   The Arm Assembly (A1)

Tissue

1. Create the Mold (for one arm)

   a. Mix 1 part of Alja-Safe® Alginate to 1 part water to a creamy consistency with no lumps.

   b. Pour the solution into the cylinder.

   c. Suspend your arm in the mold ½" from the bottom of the cylinder's walls. It is recommended to shave and grease hand with mold/casting lubricants before molding.

   d. Carefully retract your arm after 10-12 minutes once the mold has set.

2. Create the Casting

   a. Mix 1 part of Dragon Skin 30 with 1 part of deionized water, and 1 part of Slacker. (Optional: Use this color scheme to obtain the casting color desired:

   b. Place the silicone rubber mixture under 29 inches of mercury for 2-3 minutes.

   c. Pour the mixture immediately into the mold using the techniques described (for improved casting quality) until it crests ½" (~1.3cm) over the mold. Let it cure for at least 16 hours under room conditions.

   d. Carefully remove the casting from the mold. The mold can be used for one more casting.

Bone

1. Create the Bone

   a. Measure and label the following dimensions on the face of the plank (the width of the molded arm minus a ¼") on the length, (the length of palm minus a ¼"); on the side (width of arm minus 23"). Cut along the labels and ignore the saw thickness.

   b. Tap two holes, size (something) from the center, in the wrist and forearm panels.

   c. Fit the invisible hinges. Shim or trim accordingly

   d. Form the forearm panel to meet this shape approximately:

   e. Tap five holes in the palm panel. Shape and fit the copper piping to the tapped holes.

   f.   Fit and secure the plastic piping in the following manner.

6.2.   The Pump Assembly (A2)

Tools Needed: Peristaltic pump.

1. Obtain a container and fill with water.
2. Prime the tubing with water

6.3.   The Electronic Assembly (A3)

1. Setting up the Arduino Uno Board and breadboard.
   a. Connect the output channel on the Arduino Board to the base leg of the transistor with the resistor in series.
   b. Connect the collector leg of the transistor to the ground leg of the transistor.
   c. Connect the emitter leg to the ground channel.
   d. Connect one leg of the solenoid to the collector leg of the transistor.
   e. Connect the diode's positive closest to the solenoid's leg and its negative to the collector leg in series.
   f. Connect the transistor's leg to the
2. Programming Arduino
   a. Download the Arduino Program compatible for your computer here http://arduino.cc/hu/Main/Software.
   b. Load the Blink file from the File>Examples>1.Basics>Blink pathway on a Macintosh.
   c. Edit the delay input for the high voltage to "200".
   d. Edit the delay input for the low voltage to "1000".

7. Final Design and Validation

Assemblies were successful proof of concepts that demonstrated the functionality of each of the objectives however; there were some complications in fitting them together. Further evaluations will need to be assessed to diagnose these problems. This experience gives insight to what functions are truly valuable through user interviews.

8.   Discussion

This project has been an educational experience as required to fulfill a bachelor's degree. Besides implementing some scientific and engineering knowledge, there has been some interface with economic, political and regulatory bodies that effectively connects the academic study and societal domains. Many of these interactions made outside the academic institution were guided by our advisors, and it's my suggestions that any undergraduate student at WPI should seek to make these connections prior to undergoing a MQP. It lays a defined landscape, though not thorough, for students to attain information easily than without first making those connections. For example, it should have been expected that there would have been some inquiry of how to produce many RALP simulations. Contacts in the manufacturing business, which are numerous in Worcester, would have been helpful in obtaining relevant information on the process of manufacturing a few to many models, in a particular amount of time, at a specified quote. That is not to ignore the many resources available on campus however. Many professors and faculty have access to equipment in making simple models, acquiring materials and business contacts that would improve on the design process. Overall, there are no superficial societal, political, ethical, health & safety concerns implicated with the development provided in this report. Sustainability and recyclability concerns will need to be established with further development.

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