Design, Testing and Calibration of a Small Syringe for Use with a Power Injector

Final Report

May 4th, 2011

Team Members
Chris Besaw: Team Leader
Steve Young: Communicator
Don Weier: BSAC
Joe Benert: BWIG

Client
Dr. Charles Strother

Advisor
Professor Paul Thompson

Abstract

The client, Dr. Strother, is a specialist in angiographic imaging research. His work deals predominately with small animals, where there is a lack of angiography equipment suitable for injecting contrast medium for the procedures being performed. Angiography is a procedure in which images of blood vessels are gathered using a contrast fluid in conjunction with a medical imaging scanner. The contrast medium is injected near the point of interest allowing for clear, sharp images to be gathered. In the case of small animals a smaller volume of contrast delivered at a high rate is necessary, but current market devices are designed for much larger animals. In an effort to alleviate this problem, Dr. Strother has created a rough prototype syringe capable of small volume injections. However, his design is problematic. Specifically, air bubbles in the medium are difficult to detect and remove, the device itself is cumbersome, and the range of the device does not fall between the desirable values of 0.1 and 2.0 cc. Furthermore, there is no calibration to associate the volume injected with the readout of the injector so the procedure has to be done based on visual approximation alone. The team has developed a twist-lock protruding syringe designed to solve these issues. The prototype was tested and calibrated so desired injection parameters can be converted to settings used with the power injector. Following testing, the team determined what future work needs to be done in order to improve the device and potentially bring it to market on a large scale.

Table of Contents

Background

Client Description

The client, Dr. Charles Strother, works in the Department of Radiology at the UW School of Medicine and Public Health. He is conducting research at the Wisconsin Institutes for Medical Research which involves the use of angiographic imaging. He proposed this project in order to develop a device that can be used with the power injectors he currently uses to safely and effectively perform angiographic studies on small animals used in his research.

Angiography

Angiography is a medical imaging technique used to visualize blood vessels in key areas of the body for diagnosis and treatment of medical conditions. It can be used for identification and study of multiple conditions including aneurysms, atherosclerosis disease, arteriovenous malformations in the brain, and pulmonary embolisms. Common areas of interest are the brain, kidneys, pelvis, legs, lungs, heart, neck, and abdomen. Angiography is performed using one of three imaging technologies: x-rays with catheters, computed tomography (CT), and magnetic resonance imaging (MRI). The presence of a contrast agent, a material that has a different opacity than soft tissue, is often required to produce the pictures [1]. Typically, water soluble iodide is used during x-ray procedures to make blood vessels opaque, and paramagnetic substances are used during magnetic resonance imaging [2]. A particular technique commonly employed in angiographies is digital subtraction angiography (DSA). In DSA, one image is taken before contrast agent is present and a second image is taken once contrast agent is present. The first image is then digitally subtracted from the second image to eliminate images in regions that do not contain contrast. This allows blood vessels containing contrast agent to show up very clearly in images [3].

Catheter angiography, or x-ray angiography, is very similar to regular x-ray exams. X-rays are absorbed by the body to varying degrees depending on the specific location on the body at which the procedure occurs. Dense bone absorbs a large amount of radiation while softer tissues allow a larger percentage of the x-rays to pass through. Consequently, bones appear white on x-rays, soft tissues appear as shades of gray, and air appears black. In catheter angiography, a catheter is inserted into an artery in the groin or arm. Contrast agent is injected via the catheter. Once the contrast agent has reached the blood vessels of interest, the area is exposed to small bursts of radiation to record an image on a film or digital image recording plate. Contrast agent is opaque to x-rays; thus blood vessels containing contrast agent appear bright white in images [1].

Computed tomography (CT) angiography also uses x-rays to form images but is able to produce three-dimensional images. In CT angiography, contrast agent is injected into a peripheral vein. Then, the subject is exposed to numerous x-ray beams and absorption is measured by a number of electronic x-ray detectors to produce a large number of two dimensional cross-sectional images. These images can then be compiled to create multidimensional views of blood vessels. CT angiography is less invasive than catheter angiography, because it does not require a catheter to inject contrast agent into a large artery or vein. CT angiography also produces more precise and detailed imaging of blood vessels than MRI angiography [4]. However, it does not eliminate the exposure to x-rays.

Magnetic resonance (MR) angiography, unlike the previously mentioned methods, does not use x-rays or radiation to form images. Instead, it uses powerful magnetic fields and radio waves. Wire coils in the magnetic resonance imaging (MRI) machine establish a magnetic field as electric current is passed through them. Then, while the subject is inside of this magnetic field, radio waves are sent and received by other coils in the machine. This redirects the axes of spinning protons, the nuclei of hydrogen atoms in the subject, which produces signals that are detected by the coils. These signals are used to generate images of thin slices of the subject, which can then be studied from different angles. Once again, contrast material is needed in this procedure to produce images of blood vessels. Contrast media is introduced intravenously into a vein in the subject's hand or arm. Benefits of this method are that MR angiographies are non-invasive, do not require exposure to ionizing radiation, and are less expensive than catheter angiographies [5].

Power injectors are used to effectively and efficiently deliver contrast agents during angiographic procedures. Power injectors are devices which can be programmed to deliver set amounts of contrast agent at set flow rates in a reproducible manner. They are able to provide a tight bolus of media, which enables maximum enhancement and visualization of images without unnecessarily wasting any contrasting agent. They also enable controlled and precise timing of the delivery of contrast agent so that contrast agent is in the correct location when images are taken. Since imaging technologies can take images very quickly, it is very important that the bolus of agent is in the appropriate place when images are being collected. As mentioned before, power injectors can be set to deliver consistent flow rates and volumes, making injections easy to customize for specific studies or patients. Power injectors are made of a head into which syringes filled with contrast material are inserted, plungers to dispense contrast from the syringes, tubing leading from the syringes to the patient, and a computer control unit where flow rates and volumes are set. The starting and stopping of injections are also controlled from this control unit [6].

Current Devices/Treatments

Although there is a wide availability of syringes for use with power injectors, none currently allow for injections of small (1-2 cc) volumes and thus their use is limited for small animal studies.

Hand Syringes

Handheld syringes have been used to deliver small volumes of contrast medium for angiographic procedures. These are typically limited by a lack of adequate power. These injections require power that is often in excess of manual capabilities. It is also difficult to handle the syringe and simultaneously monitor other parts of the injection procedure. This leads to suboptimal imaging during angiographies. Cardiovascular Innovations has developed a handheld syringe that addresses many of these issues. It uses a lever system to drive the plunger into the syringe barrel, and allows use of the entire palm to grip the handle, which allows for greater degrees of pressure. [7] However, this design does not meet our client's request that the device be compatible with a commercially available power injector.

200 cc Syringes

To solve the issue of injection power, one current device used for angiographies is power injecting 200 cc syringes. They work with a battery powered injector to deliver specific volumes of contrast for larger animals, including humans. This device is efficient and offers control of multiple variables, including delayed start, volume delivered, concentration (it mixes from a syringe of contrast and a syringe of saline to change concentration), flow rate, and injection time. [8] However, this volume is too large to be precise enough to work with small animals, so it cannot be used in this application without modifications.

Covidien Optistar LE MR Injector

Another large volume syringe injector has been created by Siemens. Their LE MR injector is designed to work with 60 cc syringes for MRI contrast delivery. It is an AC powered injector consisting of dual syringe power heads and a full color touch screen (Figure 1). This device allows for timed contrast single bolus and dual phase injections of contrast medium. [9] Again, the major problem with this design is that the volume is too large, so modifications would be necessary.

Figure 1: Siemens LE MR power injector. [3]

Client's Prototype

To address the volume issues of the larger syringes, our client has designed a prototype 1 cc syringe which can be used with the current 200 cc syringe and software. This prototype has a 1 cc syringe fitted within a 200 cc syringe. The plunger arm of the 1 cc syringe attaches to the 200 cc syringe's rubber plunger, as shown in Figure 2. Preliminary testing has revealed that some modifications to this design may result in a workable device, but problems currently exist. Air bubbles commonly occur when loading the prototype, and are sometimes difficult to identify. Construction limitations result in an inability to extend the plunger arm to its maximum length. Additionally, the device is not calibrated with the software designed for a 200 cc syringe, so the amount of volume injected is not easily known. [10] These issues must be addressed before this design becomes a viable option.

Figure 2: Client's Prototype

Digital Subtraction Angiography Micro-injector

Digital subtraction angiographies offer an appealing approach to imaging in small animals because of high spatial and temporal resolution and the ability to visualize and measure blood flow. In a design by De Lin et. al., a micro-injector for use with this imaging technique was developed. It uses N_2 triggered by computer software to push contrast through a zero dead volume direct lift solenoid valve. The contrast agent is stored in a heated reservoir to reduce viscosity. This system is designed to inject precise amounts of contrast at high flow rates into specific areas. [10] Although testing has shown that this design is capable of delivering repeatable small volumes, it does not meet the client's vision of a product compatible with a commercially available power injector.

Problem Motivation

Our client's request for the design, construction, and calibration of a small volume power injecting syringe arises from the need to be able to inject contrast medium into small animals for angiographies. Devices currently exist for use with large animals, including humans, but there is nothing effective for small animals, such as rats. Larger syringes cannot be used to deliver small volumes of contrast with the precision necessary for angiographies. Hand syringes have been previously used, but they lack the precision of a machine controlled injector and the pressure needed to deliver the contrast to the final location. Our client's prototype, designed to rectify these problems, introduces new problems with air bubbles which can form clots blood vessels, or precipitate strokes, potentially leading to death. Furthermore, the software designed for use with a 200 cc syringe does not display the volume of contrast held in the one cc syringe. As a result, our client would like us to develop a prototype which accounts for these issues.

Design Requirements

Our client's work requires precise injection of contrast fluids into lab rats in order to perform effective angiograms. The syringes currently used with the power injector in his lab, the Accutron HP-D, do not meet his needs for small animal injection. They lack certain qualities relating to accuracy, utility, and safety that our design will need to fix.

Because the syringe will be used to inject small amounts of fluid, as small as 0.2 cc, it will need a level of accuracy that is not found in larger syringes. To address this problem, the design will have a margin of error no larger than 3 percent. The design must also be accompanied by a calibration chart and a user's manual instructing the device operator how to properly perform angiographies using the design. The calibration chart will offer the user a simple

The design itself must be user-friendly, simple to implement, and cost-effective. By following the appropriate design requirements, the prototype will be marketable, practical, and more able to satisfy the client's need. First, the design must be retro-fit to the Accutron HP-D. In accomplishing this goal, the power-injector's software cannot be altered, and the machinery of the pistons themselves must remain unchanged. To improve on the current prototype, the design needs to withdraw the plunger of the smaller syringe fully when the piston is entirely pulled back. Second, the components of the design that come in contact with the fluid should be disposable and should be able to withstand the temperature and pressure of an autoclaving machine. Another necessary trait in the design is visibility. The current design obscures the view of the smaller syringe. This design flaw gives rise to two problems: the measurements on the syringe are difficult to see, and air bubble detection and removal is extremely difficult and many precautionary steps must be taken to ensure the safety of the subject. These air bubbles, if not removed, can cause serious complications in the injected organisms. While incorporating these requirements, the mechanism should not cost more than ten to twenty dollars, which is the average cost of a power injector syringe on the current market.

In addition to these specifications, the product must also meet certain safety requirements. One concern raised is that the design should be latex-free so as not to trigger allergies in the test subjects or staff. In addition to a latex free composition, the design must also include a safety lock, so that the piston does not accidentally overdrive and cause complications in the Accutron HP-D or cause injury to the operator.

Design alternatives

In order to solve the problems with the current methodology of small-animal angiography illustrated above, the design team devised three potential models. Each of these three ideas is original in nature and has advantages and disadvantages over each other.

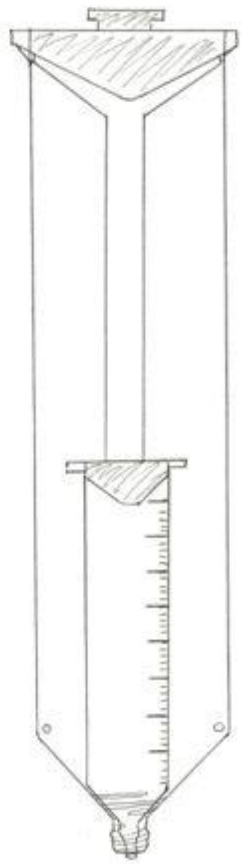


Figure 3: Center-Mounted Syringe

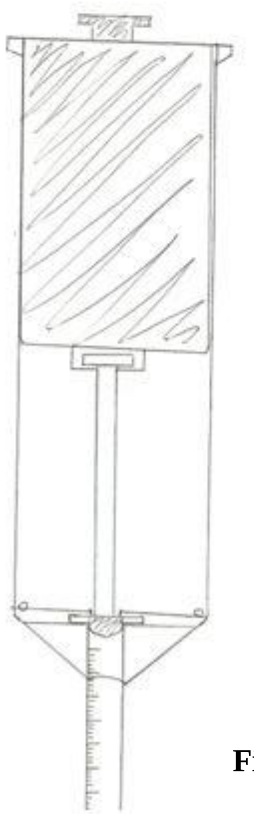
Center-Mounted Syringe

The first design, shown in figure 3, was created to mimic the current syringe prototype in style, with a few alterations. The small, inner syringe will be larger than that in the prototype to ensure the necessary dispensable volume range is met. This range is 0.1 cc to 2.0 cc, so the design incorporates a 2 cc syringe into the sketches. The smaller syringe is mounted permanently into the larger syringe in the prototype, which poses loading problems. Consequently, in this design, the 2 cc syringe will be mounted in a twist-and-lock mechanism that allows syringe removal for loading. Loading outside the larger syringe saves considerable time and energy and is much less cumbersome. The 2 cc syringe will be positioned directly in the center of the larger syringe, which allows the plunger to apply a force directly in the center of the syringe. The change in syringe size will not require an alteration of the larger, 200 cc syringe, because the entire inner syringe will be encompassed by the outer syringe. The plunger of the smaller syringe will be attached to the larger plunger mechanized by the machine itself the same way as the prototype. The plunger will slide into a slit that is designed to provide stabilization, but also easy removal.

Figure 4: Side-Mounted Syringe

Side-Mounted Syringe

The second model incorporates the inner syringe being attached to the outer syringe and a tube drawing the contrast medium out of the larger syringe. The 2 cc syringe will be fastened to the outer syringe with a collar-type mechanism. This system ensures that it is easy to see into the inner syringe to detect air bubbles. Because the inner syringe is positioned off-center in the larger syringe, the 200 cc plunger will have to apply force near its edge. A different method of plunger attachment is therefore necessary. The slot method will work, but will need to be positioned near the edge of the larger plunger with similar stabilization support and assembly. The tubing connecting the 2 cc syringe and the catheter tubing must be flexible enough to maneuver from the side of the larger syringe out the tip.



Protruding Syringe

This design features the 2 cc inner syringe protruding from the mouth of the larger, 200 cc syringe. In order for this design to work, it will be necessary to cut off the tip of the larger syringe, so the 2 cc syringe can fit through the mouth of the larger syringe. The smaller syringe will be fastened into the larger syringe with the same method as the center-mounted syringe: a twist-and-lock mechanism. The syringe will be able to be removed easily because of this method of attachment. The plunger will need to be lengthened to fit the new position of the smaller syringes thumb press, because the small syringe plunger does not reach the same length as with the other two designs. The same slotting mechanism as the current prototype will be used to attach the 2 cc syringe plunger into place.

Figure 5: Protruding Syringe

Design Matrix

In order to assess the viability of each of these three designs for use in small-animal angiography, a comparative examination of the three proposed models was conducted with a design matrix, shown in Table 1 below. The design matrix provided a quantitative analysis of which idea would transition best to clinical use. The five categories used in the design matrix were accuracy, ease of manufacturing, air bubble detection and removal, compatibility with the machine, and ease of sterilization. Based on the point breakdown listed below, the protruding syringe design received the largest allotment of points, so the team has chosen to move forward in the design process with this model.

Table 1: Design Matrix

The maximum point values are indicated in the parentheses in the row headings. The protruding syringe will be used as the primary design in the coming weeks of the project.

	Center-Mounted	Side-Mounted	Protruding Syringe
Accuracy (30)	22	25	29
Air Bubble Detection and Removal (25)	8	5	5
Ease of Manufacturing (10)	16	22	21
Ease of Sterilization (20)	14	10	12
Compatibility with Machine (15)	17	10	17
Total (100)	77	72	84

Accuracy

Accuracy was allotted nearly one third of the total points available, because of its importance in the application of this device. When working with such small volumes of contrast medium, it is especially important to deliver an exact amount. Too little medium will result in blurry pictures, while too much medium can result in death of the subject. The first method, the center mounted syringe, received the fewest points of the three, because as the diameter of the syringe is increased, the results become less accurate. The protruding syringe did the best in this category, with almost perfect marks, because the design allows for a slim syringe which is conducive to accurate measurement. The side-mounted syringe scored between the other two designs, because it has the same length syringe as the protruding design, but the extra tubing connecting the syringe with the catheter tubing results in more error.

Ease of Manufacturing

Ease of manufacturing was given 10% of the points available, because all of the designs would be relatively easy to manufacture. However, the protruding syringe design and the side-mounted syringe model received about half the available points, because they involve incorporating different modifications into the finished product. The protruding syringe will require the tip of the 200 cc syringe to be cut off, while the side-mounted syringe will entail the insertion of tubing connecting the syringe to the catheter tubing. The center-mounted syringe received nearly all of the points, because no major changes will be made from the original prototype.

Air Bubble Detection and Removal

One quarter of the total points was given to the detection and removal of air bubbles, because it is a vital step in the angiographic process. When bubbles are injected with the contrast medium, there is a much higher likelihood of subject death. The easiest way to prevent this from happening is to find the air bubbles and remove them before injection. The center-mounted syringe received the lowest amount of points in this category, because the syringe is placed in the center of the larger, 200 cc syringe, making it harder to see. The protruding design received 21 points, because the syringe is positioned mostly out of the larger syringe, making bubble detection relatively easy. The part of the syringe that is still contained by the large syringe will be harder to see, however, and still poses some problems in this category. The side-mounted syringe is pressed against the wall of the larger syringe, which will allow the user to see the air bubbles formed much more easily than if the syringe was placed at the center. However, the user is still required to see through two layers of material, which could make it difficult to detect all the bubbles. Air bubble removal of all three designs is easy, because the syringe is removable.

Compatibility with the Machine

This category received 15% of the total possible points, because it is important for the design chosen to work with the machine. Since the machine cannot be altered in any way, the device must work with all current procedures being performed. The center-mounted syringe received the most points, because the outer design is no different than the prototype that works well with the current machine. The side-mounted syringe got the lowest amount of points, because the tubing connecting the syringe to the catheter may not be compatible with the machine. The protruding syringe must be altered, because the tip of the 200 cc syringe must be removed, which could pose some problems, so it received 12 points.

Ease of Sterilization

The syringes used in angiography must be sterilized every time before their use to prevent the spread of infections to the subject. Consequently, the ease of sterilization was allotted 20% of the total points. The side-mounted syringe received the lowest number of points, because it will be most difficult to sterilize both the syringe and the tubing connecting the syringe to the catheter tubing. Both the center-mounted syringe and the protruding syringe received the same amount of points, because the removal of the syringes to sterilize them is easy, and there are no other parts that need to be sterilized.

Final Design

The final design consists of three main pieces: the housing unit, the stopper, and the 2 cc syringe. The housing unit is a 200 cc syringe with a small portion of the bottom of the cut off to allow the 2 cc syringe to protrude out. A twist and lock mechanism was implemented inside the housing to hold the 2 cc syringe during use. This twist and lock mechanism consists of three homopolymer polypropylene disks. These disks were ordered from Protolabs using their Firstcut rapid prototyping system. Homopolymer polypropylene was selected to be the material used for these disks, because it has a high strength to weight ratio, and the material is chemically resistant. The top and bottom disks are fitted tightly to the walls of the housing unit and are held in place with epoxy resin. The middle disk is free to rotate. Holes are cut in the three disks such that the 2 cc syringe can be placed into the mechanism and twisted into place so that vertical and horizontal motion of the syringe during operation is inhibited. Holes are drilled in the housing unit to prevent any pressure from building up inside the housing during operation.

The stopper is made of Delrin 150 and allows the piston of the power injector to effectively move the plunger of the 2 cc syringe. This stopper was also ordered from Protolabs using the Firstcut system. Delrin 150 was used, because it is chemically resistant, smooth, rigid, and easily machineable. Attached to one end of the stopper is a slotted piece into which the thumb press of the 2 cc syringe is secured during use. Attached to the opposite end of the stopper is the protrusion that fits into the power injector piston, making the device compatible with the power injector.

The 2 cc syringe is a Red Nitro W. P. Custom Syringe ordered from Merit Medical. As mentioned previously, the thumb press of the syringe is inserted into the slot on the stopper and the syringe itself is placed in the twist and lock mechanism to be held in place during operation.

Prototype Testing

Calibration Testing

In order to assess the performance of the prototype and create calibration equations and charts, the team conducted a series of injections with the power injector used by Dr. Strother for angiographies. The fluid used for the injections over the course of these experiments was 0.9% sodium chloride irrigation fluid, because it was available in larger volumes than the contrast medium and easier to work with. The team validated that the calibration curve remained accurate when using actual contrast medium used in angiographies by performing several test injections with the contrast medium and comparing the results to the sodium chloride curve. Volumes that needed to be measured during testing were determined gravimetrically using a scale. Using measurements from several known volumes, the density of the testing fluid was calculated so that volumes dispensed by the prototype in subsequent tests could be determined.

The first test performed was volumetric calibration, with the goal of deriving a method for equating volumes dispensed by the syringe with volumes specified in the power injector's computer. A series of seven dispensations were performed, with the volume dispensed (according to the value displayed on the power injector's computer) ranging from 10 mL to 70 mL at increments of 10 mL. Flow rate was held constant at 30.0 mL/s over the course of these seven trials. After each dispensation, the actual volume dispensed was determined gravimetrically using the electronic scale and previously determined density of the testing fluid. This data was used to construct a calibration curve, which can be seen in Figure 6.

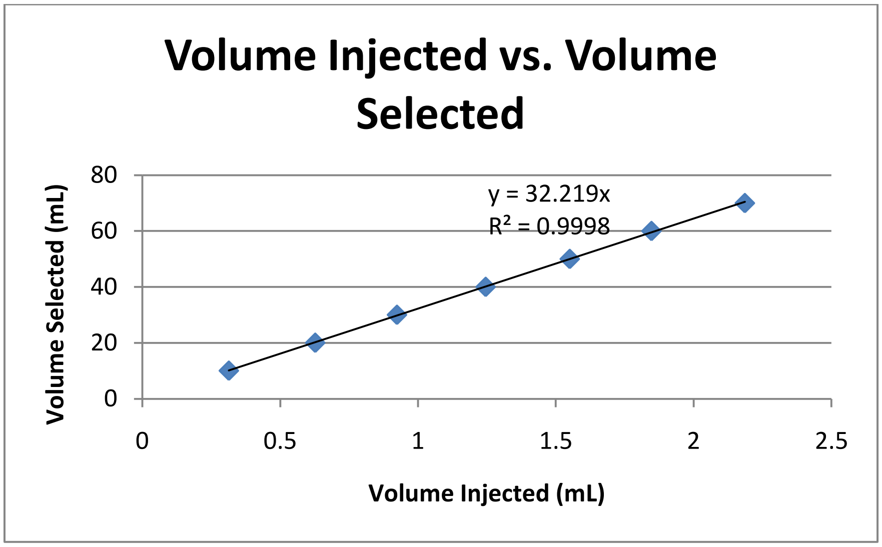


Figure 6

As can be seen in Figure 6, the data points yield a linear correlation between the volume selected and the volume injected, while an R^2 value close to 1 indicates good precision in the results. The resulting calibration curve yielded the following equation for relating volumes to be injected with volumes to be selected in the power injector's computer:

$$Selected\ Volume = 32.219 \times Desired\ Volume$$

This equation allows a user to utilize the desired volume of contrast medium for an injection to calculate what volume to enter into the computer quickly and easily.

The second test performed was flow rate calibration, with the goal of deriving a way to equate the flow rate desired for an injection with the corresponding flow rate entered into the computer. For these trials, the volume dispensed was held constant at 60 mL (as read from the computer). The maximum flow rate the power injector can deliver is 30 mL/s, so ten dispensations were performed, with flow rates ranging from 30 mL/s to 3 mL/s at 3 mL/s increments. The machine itself timed injections, and the equation determined in the volumetric calibration was used to calculate the actual fluid dispensed. Using the measurements of injection duration and volume dispensed, the effective flow rate of the dispensation was calculated for each trial. This data was used to construct the calibration curve, which can be seen in Figure 7.

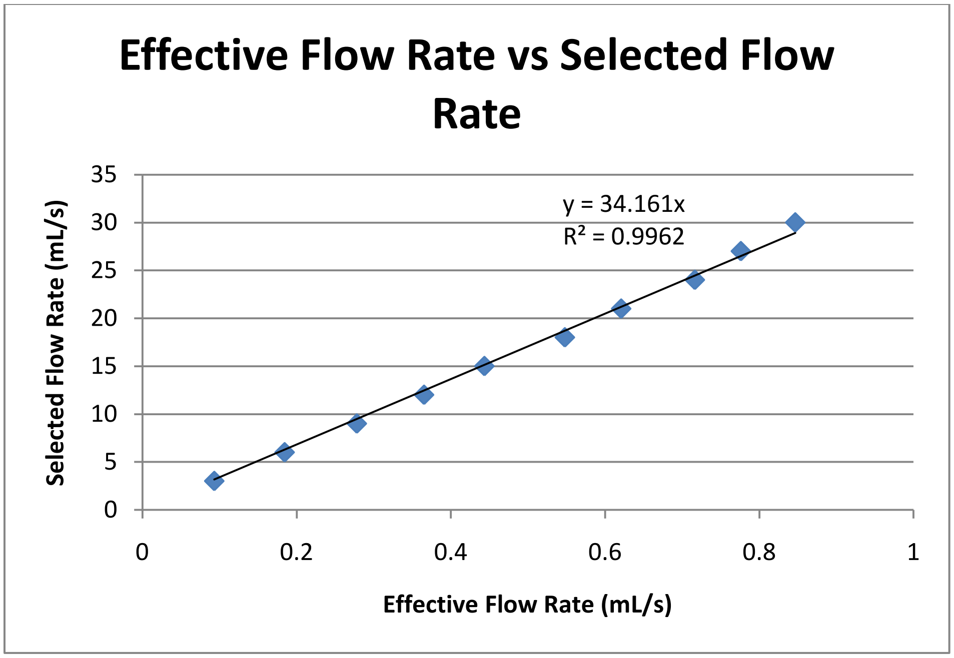


Figure7

Once again, the results yield a linear correlation between data points, and an R^2 value near 1 indicating that the derived equation is a good fit. The following equation for relating the desired flow rate to the flow rate that must be entered into the computer was derived from the data collected:

$$Selected\ Flow = 34.161\ \times Desired\ Flow\ Rate$$

This equation allows the user to apply the flow rate they desire for the injection to calculate what flow rate should be entered into the computer. Both this flow rate equation and the volume equation were included in a user's manual written for device. In addition, the equations were used to make tables of desired outputs with required inputs for quick reference, which were also included in the user's manual.

Efficiency Testing

Other important focus areas for testing of the prototype were the ease of use and efficiency of the loading process. One of the original prototype's major flaws was that it was very difficult to load the small syringe with contrast medium, because the inner syringe could not be loaded manually, making air bubble detection and removal extremely difficult. The goal of this portion of the testing was to determine whether the prototype built by the team significantly decreased the time required for loading and whether it made air bubbles easier to identify and remove.

In order to effectively test these areas of operation, the team showed seven subjects that were familiar with the angiographic process and power injector how to use the prototype. Each subject was then asked to load the prototype with the sodium chloride fluid as if they were performing an injection, with no air bubbles present in the fluid. Each trial was timed; the average time needed to load the new prototype properly was 37.9 seconds. Originally, the team had planned on having the subjects load the device developed by Dr. Strother and time those trials as well, but early on in testing the device broke, rendering it ineffective. The one recorded trial with this old prototype required 2 minutes 47 seconds for the syringe to be loaded, which was relatively fast for this type of loading. However, it was determined that the speed of loading Dr. Strother's prototype was limited by the fact that it requires the piston of the power injector to be fully extended, and then completely retracted at least once in order to draw in fluid. This process alone takes about 2 minutes, and oftentimes a careful process of extending and retracting the piston is required to successfully load the device without bubbles in the medium. Therefore, the team decided it is acceptable to conclude that the new prototype significantly decreases time required for loading.

After using the prototype, a survey was administered to all of the subjects to assess the performance of the device. The questions used in the survey, the rating system used, and the average responses are shown below in Figure 8.

1 = Strongly Disagree, 2 = Disagree, 3 = Neutral, 4 = Agree, 5 = Strongly Agree

The product was easy to use	5
The product performed the task at hand satisfactorily	5
The product was well suited for its purpose	4.88
It was easy to identify bubbles in the medium in the loaded syringe	4.71
It was easy to load the syringe without air bubbles in the medium	4.43
I would use this product in the future	4.71

Figure 8

The prototype received high marks in all categories surveyed. All of the subjects thought that the new design was much better and made loading of contrast much easier.

Cost

The fabrication and testing of the small volume syringe designed this semester cost the team a total of $477.15. This is the cost of the material and machining required to construct the plunger and polypropylene disks. The rest of the supplies needed for the project were generously donated by our client, Dr. Strother, including four 200 cc syringes, six smaller syringes, and the acrylic material used for the slot mechanism. Each 200 cc syringe costs $24, the 2 cc inner syringes cost $2, while the acrylic used in our design costs $1. The Epoxy glue, which was used to attach the three polypropylene pieces to the inner surface of the housing, cost $4. In total, the cost of re-building the design prototype would be around $504 if all materials were purchased at the given prices.

Time Management

The time spent by our team over the course of the semester can be broken down into three segments. The first few weeks of the semester were primarily devoted to researching power injectors and how they work with regard to our project, angiographies and how they are conducted, and the various hardware needed to perform these procedures. Having this background knowledge enveloping all aspects of the project helped the team devise solutions to the problem at hand and develop three design concepts. After settling on the protruding syringe design, the team designed a three piece twist-and-lock system which allowed for a removable inner syringe. This greatly increased the efficiency and ease of use for the loading process. Fabricating and testing the prototype took the remaining portion of the semester, followed by the analysis of the testing results. Both the time efficiency and the ease of use were drastically improved when compared to the old prototype, making angiographies of small animals a much simpler process.

Future Work

Over the course of this semester, we successfully designed, fabricated, and tested a small volume syringe compatible with the available power injector with a focus on small animal angiographies. Some potential design improvements have been identified that would make the injection process much more fluid and user-friendly. The most important design aspect to concentrate on in the future is the total cost of each syringe. Fabricating the prototype cost Dr. Strother $477.15 along with donated materials, adding $27.00 if purchased. This comprehensive budget for each syringe is much too large for manufacturing on a larger scale, but with various material and fabricating modifications, the team believes that this price could potentially be lowered to around $35.00. Nearly all of the cost to construct the prototype resulted from the rapid prototyping from firstcut, and in a large scale manufacturing process, this could easily be eliminated. The amount of Delrin material used for the plunger costs about $5 [11], while the amount of polypropylene used in the twist and lock mechanism would cost around $2 [12]. Additionally, the consumer of this product would only need one base unit to conduct small animal angiogrpahies, because the 2 cc syringe is disposable. The cost of conducting multiple procedures is $2 for the disposable syringe.

The manufacturing process would also need to be streamlined and could include such improvements as one piece plungers, housing units already made with a hole in the end out of which the syringe can protrude, , and molds that would produce the twist and lock disks directly.

Furthermore, the plastics could be chosen to more easily adhere to each other, which would greatly increase the longevity of the syringe in use.

Another possible improvement to the current syringe design is altering the location of the pressure release holes drilled into the sides of the outer syringe. These holes presently are situated too far from the locking mechanism, causing an air pressure buildup once the plunger passes their location during the injection process. Potential solutions include drilling the holes closer to the aforementioned locking mechanism, or manufacturing holes in the twist-and-lock mechanism, so that, when lined up properly, air flow is possible. While the current location of the holes does not significantly affect the operation of the syringe, a different pressure release hole position would increase the ease of use of the device.

One person who tested our prototype suggested lubricating the locking mechanism for a smoother twist-and-lock procedure. Currently, when twisting the mechanism, a certain amount of force is necessary for the inner syringe to be rotated into proper alignment, and some of the testers had a small degree of difficulty accomplishing that part of the loading process. The lubricant used in this solution must not react with the polypropylene disks or the adhesive holding them into place against the inner surfaces of the 200 cc syringe.

After placing the thumb press of the small syringe into the slot mechanism located on the plunger, some loading testers had the thumb press slip out of the slot mechanism. The subjects rectified the situation by withdrawing both pieces and re-inserting the syringe into the 200 cc housing unit. A simple solution to this problem is to have a locking slot mechanism in place, so after the inner syringe is mounted onto the plunger of the 200 cc syringe, the possibility of slipping is eliminated.

The middle disk in the twist-and-lock mechanism has the potential to slip out of place when a syringe is not inserted into it. Consequently, a long t-shaped stick could be included to insert into the syringe and twisted to realign the middle disk. One more design improvement would be in the attachment of the slot mechanism to the plunger of the 200 cc syringe, which would be done with screws, rather than adhesive. This would eliminate any risk of adhesive degradation over time.

A final, more long term goal, would be to adapt the entire syringe design to become compatible with other power injecting machines involved in other imaging techniques including, but not limited to, X-ray images and CT scans. In the team’s experience, the majority of changes required to meet this goal would be dimensional changes so that the pieces in the current design fit with other sized power injector syringes. When all of the considerations explained above have been accomplished and tested completely, the design could be patented and released to the market for mass manufacturing and distribution.

Ethics

In the construction and implementation of the device, some ethical considerations need to be taken into account. In the area of animal ethics, unnecessary harm or pain should not be caused to any test subject. Because of this, a priority in the design process was ensuring air bubbles not be present in the contrast fluid, so as to limit the risk of air embolism, stroke, or heart attack in the rat.

An additional consideration in the design process was the safety of the operators themselves. The production of an unsafe injector could pose unnecessary risks to the various researchers who utilized the device. Thus, the prototype was built in a sturdy, easy to use manner. Furthermore, to eliminate any potential misuse of the injector, the team has written and included an operation manual to ensure the machine is used only in the manner it was designed for, and therefore limit the risk of misuse and unforeseen dangers that could accompany it.

References

[1] Radiological Society of North America, Inc. 2011. Catheter Angiography. Retrieved 2/28/11, from http://radiologyinfo.org/en/info.cfm?pg=angiocath.

[2] Radiological Society of North America, Inc. 2011. Contrast Material. Retrieved 2/28/11 from http://radiologyinfo.org/en/glossary/glossary1.cfm?gid=80.

[3] Webster, John G. 2004. *Bioinstrumentation*. Hoboken, NJ: John Wiley and Sons, Inc.

[4] Radiological Society of North America, Inc. 2011. CT Angiography (CTA) Retrieved 2/28/11 from http://radiologyinfo.org/en/info.cfm?pg=angioct.

[5] Radiological Society of North America, Inc. 2011. MR Angiography (MRA) Retrieved 2/28/11, from http://radiologyinfo.org/en/info.cfm?pg=angiomr.

[6] MEDRAD, Inc. 2010. What is Power Injection? Retrieved 2/28/11, from http://www.medrad.com/en-us/resources/KnowledgeCenter/Pages/WhatisPowerInjection.aspx.

[7] Akhtar, S, Johnson, K, Vallabhan, R, Shutze, W, & Rees, C, Anwar, A. A new type of handheld power syringe for cardiovascular angiography. (1999, October). Retrieved 2/19/11, from http://www.baylorhealth.edu/proceedings/11_4/11_4_akhtar.html

[8] Strother, C. (2011, January 28). Personal Interview

[9] Covidien optistar LE MR Injector. (2011). Retrieved 2/19/11, from http://www.medical.siemens.com/

[10] De Lin, M, et al. (2008). A High-precision contrast injector for small animal x-ray digital subtraction angiography. *IEEE Trans. Biomed. Eng.*, 55(3), 1082-1091.

[11] DELRIN RODS: Delrin 150 Natural, 3.000in DIA. X 12in Long Rod. (2011). Retrieved 4/16/11, from http://www.plasticsintl.com/delrin-natural-3.000in-dia.-12in-long-p-327-l-en.html?utm_campaign=Base&utm_medium=Organic&utm_source=Google

[12] Natural Polypropylene Rod. (2011). Retrieved 4/16/11, from http://www.interstateplastics.com/plastic-rods details.php?sku=PRONE&diameter=2.250&dim2=3&qty=1&utm_source=froogle2&ut_campaign=froogle2&utm_medium=na&utm_content=rod-PRONE

Appendix

Design, testing and calibration of a small syringe for use with a power injector (Power Injector Syringe)

Project Design Specifications

February 10th, 2011

Group Members: Chris Besaw, Steve Young, Donald Weier, Joe Benert

Advisor: Professor Paul Thompson

Client: Dr. Charles Strother

Function:

Angiography is a technique to produce x-rays of the inside of blood vessels, and over 1.6 million procedures are conducted yearly on humans alone. A small amount of contrast medium is injected through a syringe at the point of interest, which allows the image to show up clearly. Power injector syringes are the preferred delivery method, because they allow accurate amounts of medium to be dispensed at a constant rate. Currently, no small volume (0.2- 3 cc) syringes are available for small animal studies. Our goal is to design, construct, test, and calibrate a small syringe compatible with commercially available power injector.

Client Requirements:

- Design should deliver appropriate amount of contrast medium (0.2-3 cc) into the small animal
- Syringe must meet all medical device standards
- The device should be latex-free, clear material designed with a calibration system to prevent over-injection
- Syringe should be easy to load with contrast medium

1. **Physical and Operational Characteristics**

    a. **Performance Requirements**: The device must be compatible with current power injectors. It must successfully deliver 0.2-3 cc of contrast medium. It must be easy to use and robust enough to ensure performance during loading or while the power injector is operating. The syringe must be able to load contrast medium easily as well.

b. **Safety**: The syringe must be properly calibrated and volumes must be properly labeled. The syringe must be clear enough for identification of bubbles present in the contrast medium or any that develop during contrast loading. Prevention of air bubble development must be included in the design. The device must not break during operation in the power injector. There can be no latex in the design due to allergy concern. The syringe must be able to be cleaned and sterilized. A safety lock to prevent overdriving the piston should be incorporated into the design as well.
c. **Accuracy and Reliability**: The syringe must deliver volumes consistently for each injection sequence. The accuracy of volume delivered should be ±2-3%.
d. **Life in Service**: The syringes should be disposable and used only one time.
e. **Shelf Life**: The devices will likely be stored in a cabinet or similar space in or near the room the procedure (i.e. angiography) takes place. Components should not degrade easily over time. Typically, this is not a problem for rubbers, plastics, or glass.
f. **Operating Environment**: Environment will typically be at room temperature. The syringe will be subjected to high pressure from the power injector. Other power injector syringes are rated to 1200 psi, so the syringe must be developed to withstand high pressures as well. The device will be filled with contrast medium used for angiographies, so it should not interact chemically with such substances.
g. **Ergonomics**: The syringe will have to be easy to install and replace from the mechanism hardware. Ease-of-use is also important in the syringe design, so over-injection of contrast medium is impossible.
h. **Size**: The design must fit the current machine, which holds 200 cc syringes. No alteration to this device can be done. The actual syringe must be capable of dispensing 0.2-3 cc measurements of contrast medium into the connector tubing to the catheter.
i. **Weight**: The device has no true restrictions on weight.
j. **Materials**: The syringe must be made of clear, latex-free material to ensure that no air bubbles are developing.
k. **Aesthetics, Appearance, and Finish**: The syringe must appear professional and clean. Additionally, the device must have clear measurement markings to facilitate its use.

2. Product Characteristics

a. **Quantity**: We will produce one working 0.2-3 cc syringe compatible with 200 cc power injecting equipment.

b. **Target Product Cost**: Typical power injector syringes used in angiography procedures cost around $10-$20 per syringe, so this design will be similar to those values.

3. Miscellaneous

a. **Standards and Specifications**: The final product must meet medical device standards.
b. **Customer**: The intended user of this device will be researchers who are conducting angiographies of small animals and doctors working with patients who need angiographies done with small amounts of contrast medium.
c. **Patient Related Concerns**: The designed syringe must not over-inject the rats with contrast medium, and must prevent air bubbles from developing in the syringe from loading. The device must be ergonomic, so inexperienced administrators may be able to correctly use the syringe.
d. **Competition:** Many companies sell large syringes, but very few have developed small capacity syringes like the one being devised in this project. Therefore, there would be very little competition to this design.

<u>2 cc Power Injector Syringe User's Manual</u>

Basic operation:

<u>Manual Loading (Suggested Method)</u>

1. Manually fill the 2 cc syringe completely with contrast agent
2. If any air bubbles are present, hold syringe pointing up and apply sharp taps to the outer walls of the syringe near the location of the bubble
3. Eliminate the air bubble from the tip of the syringe by slowly dispensing the plunger
4. Remove stopper from housing unit and slide the thumb press of the 2 cc syringe into the slot in the bottom of the stopper
5. Carefully insert the syringe and stopper into the housing until the 2 cc syringe is in the twist and lock mechanism
6. Twist the protruding portion of the 2 cc syringe ninety degrees so that the syringe is locked in place (some force is necessary)
7. Place pressure jacket over the housing unit
8. Insert loaded housing and accompanying pressure jacket into power injector
9. Consult calibration literature to determine appropriate settings to program into power injector
10. Proceed with injection

<u>Loading with the Power Injector</u>

1. Pull the plunger of the 2 cc syringe out completely
2. Remove the stopper from the housing unit and slide the thumb press of the 2 cc syringe into the slot in the bottom of the stopper
3. Carefully insert the syringe and stopper into the housing until the 2 cc syringe is in the twist and lock mechanism
4. Twist the protruding portion of the 2 cc syringe ninety degrees so that the syringe is locked in place
5. Place the pressure jacket over the housing unit
6. Insert the housing unit and accompanying pressure jacket into the power injector
7. Move the piston out until the computer reads that 117 mL remain to be dispensed (i.e. dispense 83 mL)
8. Attach a catheter (prefilled with fluid) to the end of the 2 cc syringe and place the end of the tube into the contrast agent
9. Withdraw the piston slowly to 200 cc to fill the syringe
10. Consult calibration literature to determine appropriate settings to program into the power injector
11. Proceed with injection

Unloading Device

1. Withdraw piston completely to 200 cc
2. Remove pressure jacket and housing unit from power injector
3. Remove housing unit from pressure jacket by applying a small amount of force to the inner syringe
4. Twist protruding portion of the 2 cc syringe ninety degrees so that the twist and lock mechanism is in the open position
5. Pull stopper and attached 2 cc syringe out of housing unit
6. Remove thumb press from slotted mechanism

Operation Calibrations

Volume Injected

The equation to use when determining what setting to put in the power injector for the volume of the injection is as follows:

$$Selected\ Volume = 32.219 \times Desired\ Volume$$

Below is a chart relating desired volume to the volume to be selected in the computer for quick reference:

Volume Desired (mL)	Volume to Program into Injector (mL)
0.1	3.2219
0.2	6.4438
0.3	9.6657
0.4	12.8876
0.5	16.1095
0.6	19.3314
0.7	22.5533
0.8	25.7752
0.9	28.9971
1	32.219
1.1	35.4409
1.2	38.6628
1.3	41.8847
1.4	45.1066
1.5	48.3285
1.6	51.5504
1.7	54.7723
1.8	57.9942
1.9	61.2161

2	64.438
2.1	67.6599
2.2	70.8818
2.3	74.1037
2.4	77.3256
2.5	80.5475

NOTE: Volumes programmed into the injector's display will need to be rounded to the nearest mL.

Flow Rate

The equation for determining what setting to put in the power injector for the flow rate of the injection is as follows:

$$Selected\ Flow = 34.161 \times Desired\ Flow\ Rate$$

Below is a chart of relating desired flow rate to the flow rate to be selected in the computer for quick reference:

Flow Rate Desired (mL/s)	Flow Rate to Program into Injector (mL/s)
0.05	1.70805
0.1	3.4161
0.15	5.12415
0.2	6.8322
0.25	8.54025
0.3	10.2483
0.35	11.95635
0.4	13.6644
0.45	15.37245
0.5	17.0805
0.55	18.78855
0.6	20.4966
0.65	22.20465
0.7	23.9127
0.75	25.62075
0.8	27.3288
0.85	29.03685

NOTE: The flow rates programmed into the injector's display will have to be rounded to the nearest tenth of mL/second.

Troubleshooting

Injection Limits

- The maximum the piston can be withdrawn safely is to the 200 cc limit (the most it can be operationally with drawn)
- The maximum volume that can be dispensed (based on volumes used in the power injector computer) is 83 mL, or to the point that 117 mL are left to be dispensed
    - **WARNING!** Injecting more than 83 total mL as displayed in the computer will result in damage to the device and possibly the power injector

Off Center 2 cc Syringe

If in the process of putting the 2 cc syringe into the twist and lock mechanism the syringe begins to slide out of the thumb mechanism and becomes off-center:

1. Remove the syringe from the housing
2. Reposition the syringe to the center of the stopper
3. Prepare to load the syringe/stopper combination into the housing horizontally
4. Rotate the stopper so that the opening of the slotted mechanism is facing up
5. Load syringe into twist and lock mechanism

Twist and lock mechanism is misaligned

1. Insert T stick from the top of the housing into the twist and lock mechanism
2. Twist T stick until twist and lock mechanism is brought into appropriate alignment

Example Participant Survey

Participant #

For the following statements, please place an X in the appropriate space to indicate your answer:

1 = Strongly Disagree, 2 = Disagree, 3 = Neutral, 4 = Agree, 5 = Strongly Agree

	1	2	3	4	5
The product was easy to use					
The product performed the task at hand satisfactorily					
The product was well suited for its purpose					
It was easy to identify bubbles in the medium in the loaded syringe					
It was easy to load the syringe without air bubbles in the medium					
I would use this product in the future					

Please write any additional comments or suggestions on the product in the space below: