Fluid Management Injection Team

10/26/2011

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Abstract

Our client, Dr. Charles Strother, is a specialist in angiographic imaging research. Angiography is a medical imaging technique to visualize blood vessels in the subject under examination. Contrast medium is injected near the point of interest, so clear pictures are depicted. In order to deliver this contrast as well as other fluids, a manifold is used. This manifold consists of ports which connect to various reservoirs of fluid and a central line which leads to the patient. Currently, the manifold device used can be cumbersome and difficult to use, and the accompanying system can be quite disorganized. There are alternative options available, but each has its own unique issues. Therefore, designs for a new manifold, a manifold stand, and a saline monitor to help alleviate some of these issues are presented and evaluated. The final designs selected are the Multi-Piece Manifold, the Table Clamp Stand, and the Ball Stopper. Additional work to be completed during the second half of the semester includes continued research, fabrication, and testing of the presented final designs.

Background

Client Description

Dr. Charles Strother is the client for this project. Dr. Strother works in the Department of Radiology at the UW School of Medicine and Public Health. Currently, Dr. Strother is conducting angiographic research at the Wisconsin Institute for Medical Research, which often requires hand injection of contrast before imaging. He proposed this project in order to develop a more efficient and streamlined method to inject contrast in the body.

Angiography

An angiography is the medical imaging of blood vessels in the body of a human or animal. Doctors use angiographies to visualize blood flow in order to treat blood vessel conditions. Some conditions that angiography detects are peripheral artery disease (PAD), which is blockage of the arteries outside the heart; aneurysms which are enlargements of the arteries; and malformations of arteries. To view these vessels, angiography utilizes three imaging technologies; X-ray, Magnetic Resonance Angiography (MRA), and Computed Tomography (CT) [1]. However, the imaging technologies are not sufficient to view the vessels alone. For x-ray images, a radio-opaque chemical is injected into the vessel. Because it is radio-opaque, x-rays cannot travel through the liquid, thus highlighting the vessel in the imaging process. For magnetic resonance angiography, paramagnetic liquids are used. These liquids used for imaging processes are called contrast or contrast agent.

X-ray angiography, or catheter angiography, is the imaging technology Dr. Strother utilizes in his lab. X-ray radiation is aimed at the part of the body that is being examined. The machine produces radiation waves that are passed through the body, and the body absorbs the rays. Different parts of the body respond differently to the x-rays, which allow radiologists to easily interpret the images. Bones appear white on x-ray images because they absorb the much of the x-rays, whereas soft tissues show up in gray. However, since x-rays alone do not allow for imaging of certain vessels, a contrast agent is utilized. Contrast agents consisting of barium or iodide are injected into the vessels of interest. This allows for clearly defined vessels in the x-ray image [1]. To inject the contrast, a catheter is inserted into a minor vessel and is guided into the major artery of interest to inject contrast. The images are recorded on a film, or saved to a digital image recording plate [1].

The second imaging technology is Magnetic Resonance Angiography (MRA). This type of imaging does not use x-rays to view the inside of the body but instead uses a powerful magnetic field, radio waves, and a computer to produce the images [2]. However contrast agents are still used to view the blood vessels. Since the patient being examined must remain completely still during the procedure, moderate sedation is sometimes provided to patients. An electric current is passed through wire coils, producing a magnetic field [2]. Other coils placed in the machine are sending and receiving radio waves. These radio waves redirect spinning protons, which are in the nuclei of hydrogen atoms [2]. A computer processes these signals and transforms the data into an image of a slice of the body.

Computed tomography (CT) is the third imaging technology, and is similar to x-ray imaging. The process of viewing the inside of the body is the same as x-ray imaging: x-ray radiation travels through the body, enabling the physician to see bones in white and soft tissue in gray, however a CT scan consists of numerous x-rays being sent to the body, rotating all around [3]. A computer is used to stitch the large volume of data and as a result, the scan is able to produce multidimensional views of the body's interior. The main difference between CT angiography and X-ray is that CT angiography is less invasive since a catheter is not inserted into the artery. There have been improvements to the CT scans which allow for more slices to be obtained in a shorter amount of time, which allows for greater viewing possibilities [3].

Current Devices/Designs

The current devices that are used to inject contrast can be separated into two categories: power injectors and hand injectors. The client also wants to improve the current device being used to dispense saline into the manifold.

Manifold

The current device Dr. Strother uses to inject contrast into a patient is a manifold. This device can be categorized as a hand injector. A hand injector is a device that requires manual injection of the contrast into the patient. A manifold is an apparatus that collects contrast and saline from their respective reservoirs and directs them into the patient via a catheter. A manifold consists of a main line connecting to the catheter, and various valves that connect perpendicularly to the main line. These valves are connected to various sources, such as contrast, saline and a waste flush. Figure 1 below shows a 4-valve manifold at the top with valves connecting to various tubes. The catheter is connected on the far right of the manifold and the connection on the left side of the manifold is closed. A syringe is sometimes connected to this closed port to aspirate unwanted fluid in the manifold.

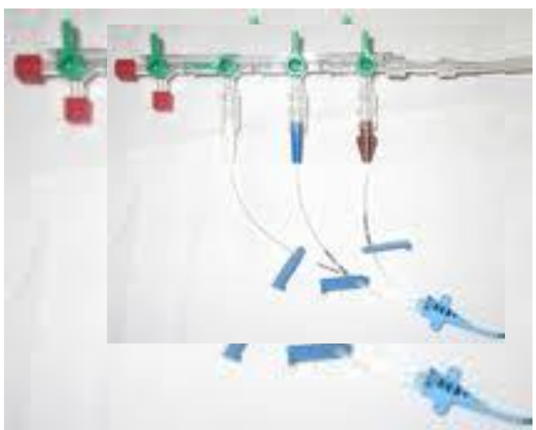

Figure 1. A 4-valve manifold shown with 3-way green stopcocks.

There are many difficulties when utilizing the manifold system, primarily poor ergonomics. The entire system which the manifold is a part of is very disorganized, with tubes covering the operating table and the manifold being placed on the patient. This increases the number of nonproductive interactions that occur, which increases the procedure time. Also, it is difficult to detect air and blood presence in the main line of the manifold. However, manifolds allow for quick repetition of trials and are cost effective.

Medrad Avanta Fluid Management Injection System

The Medrad Avanta Fluid Management Injection System is a type of power injector used for delivering contrast to a patient. It is used for a variety of cardiac imaging such as ventriculograms and aortagrams. The system can change its flow rates depending on the type of procedure being conducted. For images of smaller vessels, the system can inject contrast at low rates and low volumes, and for larger vessels or saline flushing, the system can inject at higher rates and at larger volumes [4]. The increase in efficiency from this system reduces the time of procedure, which reduces exposure to radiation to the physician. The Medrad Avanta system, shown in Figure 2, is a whole unit as opposed to a handheld, and a LCD touch screen that is connected to display information such as flow rates and pressure gauges.

Figure 2. Medrad Avanta Fluid Management Injection System

Additionally, the Medrad Avanta system features an air management system with level sensing and gross air detection [4]. This device is efficient and performs the task of injecting contrast and saline accurately, however it is very expensive, and our clients request is to improve the manifold design.

Saline Dispensing

The current method Dr. Strother uses to dispense saline to the manifold is a simple setup consisting of a sterile saline bag connected to a manifold through a tube.

Figure 3. Saline bag in pressure sleeve

Shown in Figure 3 above, the saline bag is placed inside of a sleeve. This sleeve keeps pressure on the saline bag to maintain a steady stream of saline exiting the bag. It is difficult to detect the level of saline with the current design due to the facts that the fluid is clear and the sleeve covers the bag, which could put the patient at risk of air traveling into their vessels if the saline bag is empty. The tube that connects the saline bag to the manifold is made from polyvinyl chloride (PVC) and is clear. Before the procedure, the tubing needs to be wiped to make sure no outside water drops are present. This allows easier detection of air bubbles inside the tube.

Problem Motivation

Our client's request for an improved manifold arises from a need for a more efficient, safer way to manage fluid injections for imaging procedures. The system that is currently used is oftentimes disorganized, and it is not unusual for the setup to span the entire operation room. Injections often involve large amounts of tedious work, especially since a common but difficult to control problem is fluid contamination. If air gets into the system and is not removed prior to injections, serious complications can result in the patient. In current manifolds, it is difficult to see and remove air bubbles. Another problem that can lead to time consuming backtracking is blood moving up the catheter into the manifold. If blood becomes stagnant in the catheter, it can clot. If clotted blood is re-injected into the patient, it can block an artery, presenting serious danger to the patient. In addition to this, contamination of fluid due to blood is another general concern. The imaging technology commonly used for these procedures is x-rays. Due to the length of these procedures, which can often involve over 50 injections, exposure of operators to x-rays can be a source of concern. Current devices, which offer methods of speeding up the process or presenting safeguards against the threats posed by air and blood, are relatively high-tech and very expensive. The final improved manifold design will make operations easier and more efficient. It will make air bubble prevention and detection easier and will prevent blood from moving up into the catheter and back into the system. In order to make the manifold easier to use during operations, a device will be made to hold the catheter in an easy to use location and position.

Our client's request for a method of monitoring the level of saline reservoirs arises from the frequent and integral use of saline during procedures. It is often needed for mixing with contrast for injections or for cleaning syringes and other apparatus. However, one of the more important roles of saline is the saline flush which is run through the catheter. This flush runs at all times, even when no injection is being performed, to keep blood from flowing up into the catheter. However, since the fluid is clear and the bags are kept in pressure sleeves, which serve to keep the fluid running at all times, it is often difficult to see how much saline is left in the bag. If the bag runs empty and is not quickly replaced, air can be pushed through the saline flush line and into the patient, posing a serious threat as previously mentioned. Therefore, our design will provide a means for indicating when the saline reservoir is empty as well as preventing air from moving into the catheter and thus the patient when the saline runs out.

Design Requirements

The design of the new manifold should ultimately streamline the angiographic process. This means it must allow for easy fluid management for injections. As part of this requirement, our client has requested that it be modified to work with a power injector as well as the hand syringes they use now. The components (i.e. stopcocks) must be easy to manage. The device should be space efficient and not cumbersome to the operator. The input ports should be easily accessible, and connection to fluid reservoirs should be easy to perform quickly. The manifold must be able to deliver both contrast and saline flush to a catheter and must also have extra ports to be used as needed. The new design must offer free access to the catheter lumen at all times. As a medical device, the manifold must meet the Occupational Safety and Health Administration (OSHA) standards. Since it will be a disposable device, sterilization is not a major concern. However, the device must make detection of air and blood in the fluid quick and easy. It should also effectively improve the prevention of air bubble development and blood influx to the catheter. The entire device should be easily rinsed with a saline flush at any time, and a waste removal system must also be implemented into the design. As a fluid management device, it must effectively, accurately, and reliably deliver the desired volumes of saline and contrast agent at the desired flow rates to the patient. It is used for lengthy operations as mentioned earlier, so it must be robust enough so it will not break and that components will not become disconnected during operation. Since the device will be being used in a setting in which x-rays and contrast agents are used frequently, it must be inert to both x-ray radiation and the fluids it is used to manage.

The manifold holder must be space efficient so it should not occupy a large amount of space in the operating room. It must effectively make the manifold easier to use, both in the manner it supports the manifold as well as where it allows the manifold to be placed. Since it will be close to both the subject and the fluids being injected into the subject, it must be able to be sterilized, most likely via autoclave. It must hold the manifold securely and not interfere with operation of the manifold. Since it will not be disposable, the holder must be durable and should be designed for long-term use. The material used to construct the device should be chemically inert and resistant to x-ray radiation.

The saline monitor should allow for the saline level to be assessed during use. As with the other devices, it should be space efficient and simple to use to help streamline the procedure. It must meet aforementioned OSHA safety standards, and if it comes in contact with the saline it must be sterilized. The device must also prevent the introduction of air bubbles into injected media in the case that the saline reservoir runs empty. It should be chemically inert to all liquids used in the procedure, especially saline, and should also not be affected by x-ray radiation.

Design Alternatives- Saline Dispensing

In order to solve the problems with the current methodology of saline level detection described above, the team created three potential models. Each design incorporates different means of achieving the desired result- eliminating the possibility of air injection into the patient.

Hanging Alarm Design

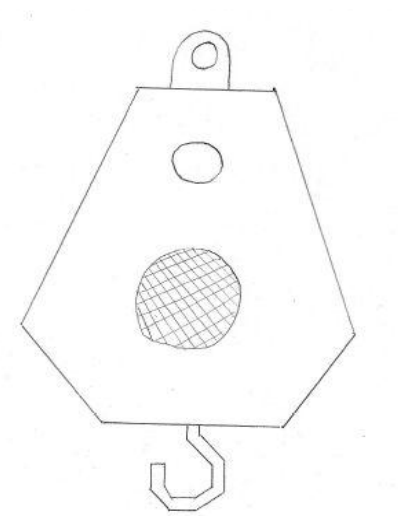

Figure 4 Hanging Alarm Design

The first design, shown in Figure 4, utilizes the same hanging saline bag, but integrates an alarm system that alerts the physician when the saline levels reach a certain volume. When the alarm sounds, the user must change out saline bags to ensure patient safety. Each saline bag has a specific weight when empty, so the alarm is triggered when the bag reaches this critical level. The weight of the bag would be measured by a hanging scale, which would be attached to the stand as well as to the top of the saline bag. A circuit accompanied by a threshold value would be connected to the digital scale, which would set off the alarm. This design would have minimal effect on the arrangement of the work space area, as the scale would be hung on the stand already holding the saline bag.

Peristaltic Pump Design

The second design, shown in Figure 5, replaces the hanging bag of saline with a peristaltic pump. The pump would be set to dispense a consistent, reliable amount of saline per unit time, and can be turned off or on at any time in the procedure. The peristaltic pump would be placed on the operating table, or on another table off to the side of the main one. This would aggravate the existing problem of space management present throughout the procedure. The saline is very easy to see in the design, unlike in the hanging saline bag, and can be added at any time. One downside is that if the saline level does reach zero, the pump will continue to push air through the tubes toward the subject.

Figure5. A peristaltic pump with variable flow

Floating Ball Design

The last design, shown in Figure 6, is very similar to the original set-up in that it utilizes the bag to deliver the saline in the procedure. An air embolism protection device is connected underneath the saline bag, which includes a floating ball in the saline present. When the level reaches zero the ball acts as a stopper to the tubing leading to the patient. Consequently, no air bubbles can be introduced to the subject, and the physicians can easily exchange bags to continue with the angiography. The ball must be sterilized before each use, as it comes into contact with the saline solution.

Figure 6 Flexible chamber with green ball at bottom

Design Alternative- Manifold Mechanics

Air bubble detection, stopcock management, and fluid control were all problems stressed by Dr. Strother, therefore major emphasis was placed on the mechanics of the manifold itself. Each design listed below addresses these issues and presents a way to improve time efficiency and the ergonomics of using the manifold in an angiography procedure.

Single Piece Design

The first design, shown in Figure 7, places a great deal of weight on space efficiency and places each manifold element in close proximity to each other. One-way valves will be incorporated directly on the manifold leading to each of the four ports. This addition to the original manifold will ensure that no blood from the subject moves up the lines toward the fluid reservoirs. The design is very simple, requires minimal set-up, and relies on the existing stopcocks to direct fluid flow from the manual contrast injections.

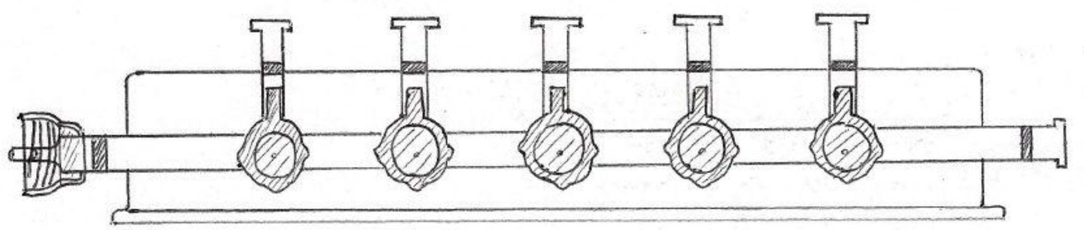

Figure 7. Single piece manifold
with 5-valves

Screw Clamp Design

The second design, shown in Figure 8, utilizes a manifold shell without stopcocks incorporated into the manifold itself. One-way valves and screw clamps are integrated into the system on each of the four port lines themselves. An advantage of this design is that air bubble detection in the manifold is extremely easy, because it is an open line with few pieces hindering its view. Additionally, air bubble formation is decreased with the design, because there are no places for the air to become trapped, as was the case with the stopcocks. The one-way valves offer the same protection from blood contamination as mentioned in the single piece design.

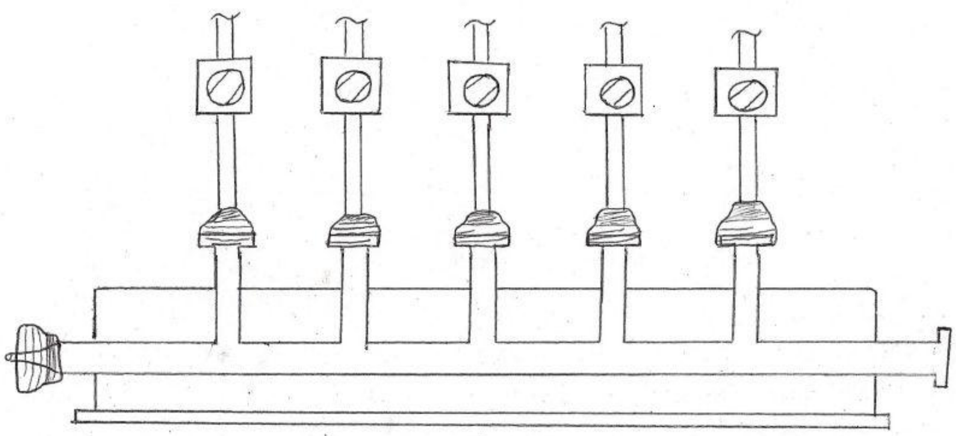

Figure 8 Manifold with square
screw clamps

Multiple Piece Design

The third design, shown in Figure 9, integrates aspects of the two previous designs, but also adds ramp clamps upstream of the manifold. These components offer graduated control of fluid flow, which is important for allowing saline and contrast through the manifold at various flow rates. Again, the manifold shell is clear of stopcocks, making the main line visible.

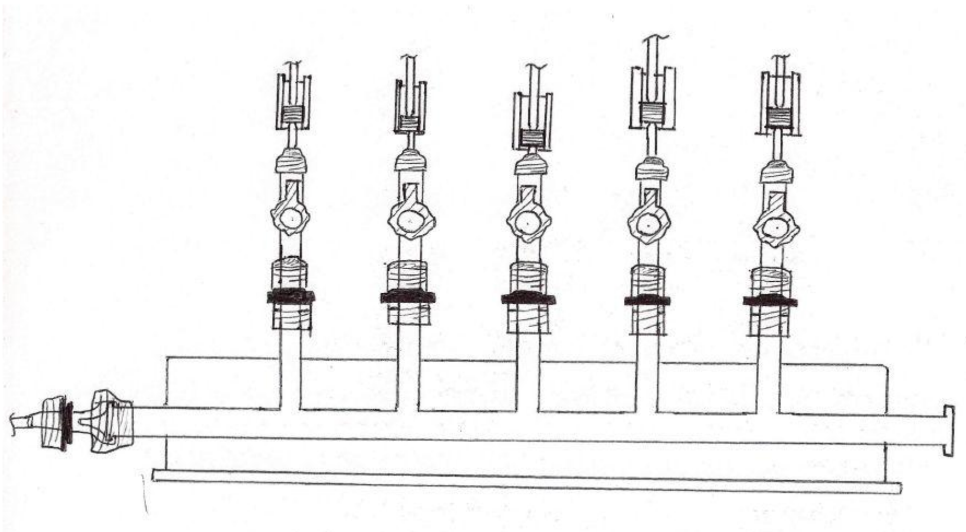

Figure 9. Multiple pieces manifold

Design Alternative- Manifold Stand

Posed with the problem of work space inefficiencies and disorder, the team devised three ways to improve the functionality of the manifold device as well as decrease the expected procedure time by eliminating nonproductive interactions with the device.

Weighted Block Design

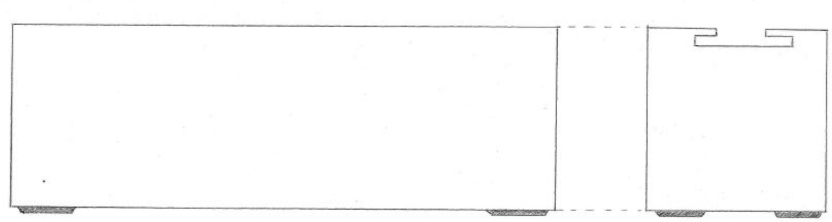

Figure 10. Weighted Box

The first design, shown in Figure 10, incorporates a weighted mount for the manifold. Dr. Strother expressed concern over the large number of manifold readjustments during a procedure, so a holder presenting more movement resistance was designed. The manifold is attached to the block through a sliding mechanism that inhibits manifold movement during use. Additionally, rubber pads will be affixed to the bottom, offering yet more motion inhibition. The block will set on the table, which will require slightly more work space than the original manifold.

Moveable Arm Design

The second design, shown in Figure 11, utilizes an arm similar to that of a desk lamp. This offers full range of motion for the manifold, as well as location fixation once the desired position is achieved. The arm will be mounted on a floor stand, so the manifold will not be on the operating table, offering more workspace for the physicians. The manifold will be held in place by a clamp at the end of the arm. This design has the advantage of having adjustable height for the device, because of the lack of fixation to the table.

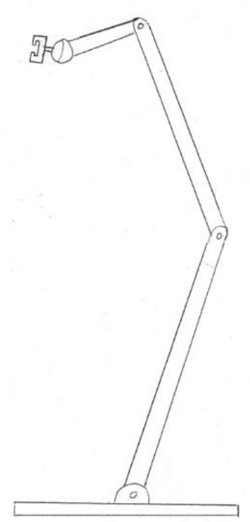

Figure 11. Movable Arm

Clamp Design

The last design, shown in Figure 12, features a moveable clamp that attaches to the edge of the operating table. The device can be placed in any location and can be moved during the procedure. The manifold will be mounted to the clamp in the same way as the weighted block, through a sliding mechanism that ensures no manifold motion once clamped down. This method offers complete stability of the manifold, unlike the previously discussed designs, and saves table space by extending the manifold off the table. The design also positions the manifold at an angle, making it easy for a person standing near the manifold to look down on it and have a clear view.

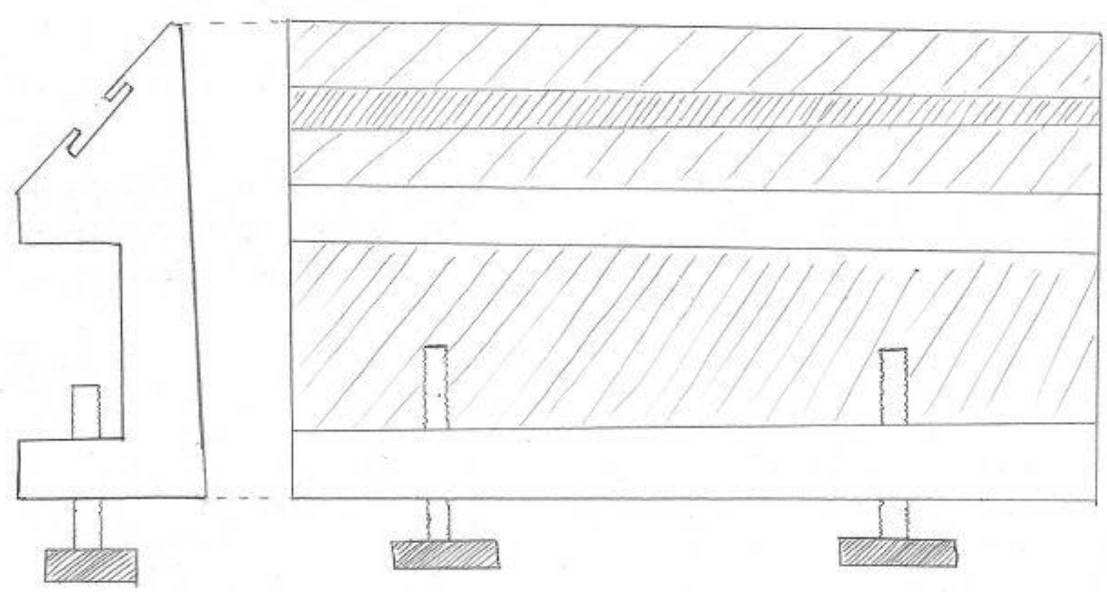

Figure 12 Clamp manifold holder

Design Matrices

In order to assess the viability of each set of three designs for use in angiography procedures, a comparative examination of the three proposed models was conducted in a design matrix, shown below. The design matrices provide a quantitative analysis of which idea would transition best to clinical use.

Manifold Mechanics

In this subset of designs, the five categories used in the matrix are ease of manufacturing, cost, contamination detection, fluid control, and set-up time. Based on the point breakdown listed below, the multiple piece design received the largest allocation of points, so the team has chosen to move forward in the design process with this model.

	‘Single piece' Design	‘Multiple pieces' Design	Screw Clamp Design
Ease of Manufacturing (25)	15	20	24
Cost (5)	4	4	5
Contamination Detection (15)	10	12	14
Fluid Control (30)	24	29	18
Set-up Time (25)	20	16	18
Total (100)	73	81	79

Ease of Manufacturing

The ability to fabricate a prototype was given one fourth of the total amount of points, because the design must be feasible to create since it is to be disposable. Any alteration of the manifold itself would be difficult to achieve, and the future manufacturing would be nearly impossible. The 'single piece' manifold received the fewest point in this category, as it involves direct modification. The stopcock handles are shortened, which requires machining, and the one-way valves are integrated into manifold itself. The screw clamp design scored the best in this category, because it entails no change in the manifold or alteration of stopcocks like in the first design. Screw clamps are simply attached down the lines off each port on the manifold, the easiest modification to the original device. The 'multiple pieces' design scored between the other two designs, because it does not involve any direct alterations of the manifold but does incorporate three other components to each port, including the one-way valve, the two-way stopcock, and the ramp clamp to control flow rate. The manifold itself will be a shell, without any stopcocks, which can be ordered pre-made.

Fluid Control

The management of the various fluids during a procedure is the most important aspect of the manifold design, because the physician needs complete control over the contrast agents and saline in order to attain sharp images in a timely manner. During the procedure, the physician is exposed to x-ray radiation, which is a concern expressed by Dr. Strother. Consequently, the amount of fluid control one has during the operation greatly reduces the time they are exposed. The screw clamp manifold displays the most precise amount of command over the various fluids but would offer the slowest operation in terms of simply opening or closing the lines completely, because the design only incorporates screw clamps on the port lines with a manifold shell. The single piece design received the next largest allotment of points, because it prevents blood from reaching the fluid reservoirs with the one-way valves and also contains the stopcocks in the main line, which allow for quick opening and closing of ports. The multiple pieces manifold received near perfect scores in this category, because it allows for regulation of flow rate, along with all the other control methods stated previously including absolute stoppage from the stopcocks and blood contamination prevention through the use of one-way valves.

Set-up Time

The set-up time required to prepare the manifold for the pending procedure is also very important to the overall design and makes up 25% of the total points available. The more complex the design is, the more time is needed for the physician to ready the operating table. The multiple pieces manifold scored the lowest allotment of points in this section, because it contains the most components which will all have to be assembled before the procedure. The screw clamp design received the most points, because it involves simply placing a screw clamp over the tube protruding from each port on the manifold. The single-piece manifold scored the highest because being one piece, it requires minimal set-up.

Contamination Detection

Air bubble and blood detection is imperative to the overall success of the procedure and health of the patient. Air bubbles that are injected into the subject can lead to harmful complications and blood flowing back up into the manifold or fluid reservoirs can clot and reinjection can cause major problems. Therefore, the design must be conducive to locating these air bubbles and blood, so this category consists of 15% of the total amount of points available.

The single piece design received the lowest amount of points, because it has stopcocks in the main line of the manifold which can obstruct the view of the user, making contamination detection difficult. The multiple pieces design was awarded the next largest portion of points, because its manifold line is clear, but it also incorporates three different components that the physician must inspect to ensure patient safety. The screw clamp scored the highest amount of points in this category, because it also uses a manifold shell but only has one component (screw clamps) to hinder air bubble and blood detection.

Cost

Cost played the smallest role in the design selection process, because the main focus is on the design's functionality. Additionally, none of the parts included in any of the designs were very expensive. The single piece and multiple pieces designs scored 4 of the possible 5 points, because they involve multiple components or alteration of the manifold. The screw clamp received all the points, because it involves placing only one screw clamp on each port tube.

Manifold Stand

The manifold stand design matrix is comprised of ease of manufacturing, cost, versatility, stability, and space efficiency. Based on the point breakdown shown below, the clamp design received the largest amount of points and is the design that will be pursued in the future.

	Clamp	Weighted Box	Moveable Arm
Ease of Manufacturing (20)	18	19	10
Cost (5)	4	5	2
Versatility (25)	20	22	23
Stability(30)	29	20	18
Space Efficiency (20)	18	16	12
Total (100)	89	82	65

Ease of Manufacturing

As noted in the first section, the design must be within the team's abilities to fabricate successfully. Therefore, this section was allotted 20% of the total points for the design. The moveable arm design scored by far the lowest in this category, because it involves creating a stand with three segments attached via various joints. The ability to move the manifold but also maintain stability would be very hard to achieve. The weighted box manifold stand would be the easiest to construct, because it entails a box weighted down by a high density material. A slotted mechanism would be incorporated as well as rubber pads to increase the stability of the stand. Both of those additions are relatively easy to assemble. The clamp is also very easy to make, scoring only slightly lower than the weighted box design. The design involves a screw clamp which affixes to the table and the aforementioned slotted mechanism.

Versatility

The ability of the manifold stand to be placed in multiple locations is very important during a procedure; consequently, this section received 25% of the total. The physician may want the manifold to change locations during an operation or vary the location from procedure to procedure. All of the different designs scored well, because they fulfill the requirements listed above. The moveable arm received the most points, however, because it can move in the z direction, which is beneficial for physicians of differing heights. The clamp manifold stand received the lowest allotment of points, because it must be fixed to the edge of the operating table to be secure. The moveable box design scored between the previous two designs in this category, because it can move anywhere on the table, but cannot be elevated.

Stability

During a procedure, when the manifold is placed in its permanent position, there must not be any slipping or moving due to other forces placed on the tubing connected to the manifold. When this happens currently, nonproductive interactions with the manifold take place, leading to time inefficiency. As stated previously, procedure time must be reduced as much as possible, so the stability of the manifold stand is very important. Stability was allocated the largest portion of the total points available with 30%. Because of its nearly flawless securing application to the operating table, the clamp design scored the most points in this section. The only way the manifold could be moved is to unscrew the clamping mechanism, which cannot happen with typical manifold operation. The weighted block scored the next largest portion of points, because its rubber pads limit the amount of unnecessary sliding that the block might perform.

The moveable arm has the most difficulty keeping the manifold in place, because the joints must be moveable, but cannot move because of a non-purposeful force on the manifold.

Space Efficiency

Disorganization and clutter are major problems during angiography procedures, as Dr. Strother has informed the team, therefore the manifold stand must not take up operating table space or surrounding environment in an inefficient manner. The moveable arm includes a stand for the actual arm to attach to, which must be positioned next to the table. This requires the physicians to walk around the stand and arm when they wish to move to the other side of the operating table. Also, the stand's platform consists of a solid block, making the device difficult to stow away after procedures. Consequently, this design was allotted the lowest score. The weighted block is positioned in various locations on the table itself, which takes up space that could otherwise be used in the procedure. This design received the second largest amount of points. The clamp manifold design scored the best, because it positions the manifold off the table, therefore reducing the space needed to set-up the necessary equipment.

Cost

The manifold stand will not be a recurring cost, so this criterion is not as important as the others, but still plays a small role in the design ultimately chosen. The moveable arm received the lowest number of points, because it involves many joints and a stand for the arm to set on, which will cost more than the simple clamp and block of the other two designs. The clamp received slightly less points than the weighted block because it is more difficult to make and requires more parts made of different materials than the simple weighted block.

Saline Bag

The design matrix shown below was used to assess the feasibility of each of the three designs for a saline bag alternative. Each design was compared and assigned values based on the categories listed in the matrix, including consistency, cost, space efficiency, safety, ease of manufacturing, and fluid level detection. Based on the point breakdown the team will be moving forward with the ball stopper design which received the largest allotment of points in the table.

	Peristaltic Pump	Hanging Alarm	Ball Stopper
Consistency (20)	20	16	16
Cost (5)	2	3	4
Space Efficiency (15)	10	14	15
Safety (25)	15	18	23
Ease of Manufacturing (15)	15	8	13
Fluid Level Detection (20)	19	14	14
Total (100)	81	73	85

Consistency

During an angiography procedure, there is a constant flow of saline running to the patient to ensure no blood travels back up the catheter. The flow of saline cannot vary to the extent that it affects this prevention technique. A consistent flow rate throughout the procedure is preferred.

This category received 20% of the total points available, because of its importance in maintaining patient safety. The peristaltic pump received perfect marks, because it uses rollers to provide a consistent flow rate throughout the procedure. Both of the other designs received 16 points, because they rely on the pressure jacket to maintain the consistent flow rate. Additionally, it is difficult to pump up the jacket to consistent pressures each time it is used.

Cost

As stated before, cost is not the determining factor of which design was chosen, but plays a minor role in the selection process. The peristaltic pump requires a higher initial cost, but does not involve any recurring costs. The hanging alarm system also requires the initial cost of the scale and alarm setup, but no recurring costs as well. The floating ball design costs virtually nothing up front, and only has minor recurring costs, so it received the highest marks in this category.

Space Efficiency

The importance of this category is described in the manifold stand section, and is similarly applied to the saline bag alternative and was portioned 15% of the total. The peristaltic pump will be placed on the operating table close to the manifold, so it was allotted 10 points. The hanging alarm incorporates an additional scale to the saline bag hanger as well as a speaker and light, so it received the second largest score. The floating ball design entails a small attachment under the saline bag with no major space inefficiencies and scored the best in this category.

Safety

The safety of the patient is an extremely important aspect of the saline bag alternative design, so it received 25% of the total points available. If air bubbles are injected into the patient, as stated before, major complications can ensue. The peristaltic pump did the worst in this category, because there is no direct mechanism to shut down the pump when the saline solution runs out. It is much easier to see the levels, but it is up to the physician to monitor the saline. The hanging alarm features a system which alerts the physician when it is time to change out the saline bags, which eliminates the need for constant monitoring of the system. The hanging alarm system thus was allotted the second largest portion of points. The floating ball design did the best in terms of patient safety, because the ball obstructs air flow after the saline levels reach zero.

Ease of Manufacturing

As stated before, the ability of the team to construct the design must be taken into consideration, so ease of manufacturing was given 15% of the total points. The peristaltic pump comes manufactured, so it received perfect scores. The hanging alarm system would require the most amount of time and effort to fabricate, because it involves creating a circuit to produce an alarm to alert the physician of low saline levels. The floating ball also comes pre-made, but must be integrated into the saline bag flow route, so it was given the second most points.

Fluid Level Detection

Although air bubble injection prevention is the most important aspect of the design, the ability of the physician to monitor the saline levels before they reach critical values is also important. The fluid level detection ability received 20% of the total allotment of points. Both the hanging alarm and the floating ball designs do not improve over the current apparatus, but fluid level detection is still possible by looking through the pressure jacket. The peristaltic pump offers the easiest visualization of the saline levels, so it received the largest allotment of points.

Future Work

Although final designs have been selected, the team would like to talk to professionals familiar with the procedures performed with manifolds and obtain their input on problems with the system or possible improvements they feel would be beneficial to the process. Additionally, Dr. Strother has agreed to either let the team observe a procedure using the manifold system or make a video of a procedure or mock procedure so that the team can further analyze possible improvements to the system. Once all this research has been performed, final adjustments to the selected designs will be made and fabrication will begin. This will include selecting components that need to be ordered, especially for the multi-piece manifold, and selecting materials to be used in fabrication of elements which will either be machined in the shop or rapid prototyped through a company. Once all the necessary elements have been gathered, the designs will be constructed. Then, methods of testing to determine whether the designs have effectively improved procedures will have to be identified and then carried out. Using the data obtained in testing, any additional improvements that become apparent will be made to finalize the designs.

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Appendix

Contrast Injection

Project Design Specifications

September 15, 2011

Group Members: Chris Besaw, Steve Young, Rafi Sufi, John Diaz de Leon

Advisor: Dr. Naomi Chesler

Client: Dr. Charles Strother

Function:

Client Requirements:

1. **Physical and Operational Characteristics**
    a. **Performance Requirements:** The main component of the device will be a manifold which will allow for easy fluid management for injections. It must be compatible with current power injectors, which will be used for contrast agent delivery. It must be able to deliver both contrast and saline flush to a catheter. However, the manifold must also have extra ports to allow for injections of other fluids. The device must allow for constant access to the catheter during use.
    b. **Safety:** The device must make detection of air and blood in the fluid easy. This can be done via sensors such as ultrasound or by making the presence of air and blood easy to see visually. Prevention of air bubble development and blood influx must also be included in the design. The device must be able to be easily rinsed with a saline flush at any time. A waste removal system must also be implemented in the design.
    c. **Accuracy and Reliability:** The device must be able to accurately and consistently deliver the desired volumes of saline and contrast agent at the desired flow rates. The device must be robust enough that it will not break and that components will not become disconnected during operation.
    d. **Life in Service:** The device is intended for one time use, so sterilization via autoclaving or chemical sterilization is not an issue. The device must be disposable.
    e. **Shelf Life:** The device should be able to remain in operating condition for long periods of time. Since the device is to be made mainly of plastics, this should not be an issue.
    f. **Operating Environment:** The device will be used in a surgical setting for x-ray procedures. It must be inert to x-ray radiation and any substance it is used to inject, which is primarily saline and contrast agent but could include other fluids.
    g. **Ergonomics:** The stopcocks must be easily manageable. Detection of air and blood must be easy to perform quickly. The device should be space efficient and not cumbersome to

the operator. Input ports should be easily accessible. Connection to fluid reservoirs should be quick and efficient to perform.

h. **Size:** The manifold portion of the device should be about 6 inches long and 2 inches wide. In essence, the device should not become cumbersome to the operator during use. The entire device, including manifold, tubing, y-connectors, etc., must be as space efficient as possible.
i. **Weight:** The manifold, tubing, and y-connectors should be lightweight.
j. **Materials:** Plastic commonly used in medical tubing and manifolds, must be chemically inert, nonreactive to x-ray radiation, and robust.
k. **Aesthetics, Appearance, and Finish:** Must look professional. Pieces must be clear for the most part, but stopcock handles should be color coded.

2. **Product Characteristics**
   a. **Quantity:** Our client requests one unit be built.
   b. **Target Product Cost:** The device should be competitive with current manifolds on the market, in the range of
3. **Miscellaneous**
   a. **Standards and Specifications:** The final product must meet medical device standards.
   b. **Customer:** The intended user of this device will be used by doctors and researchers who are performing diagnostic and interventional angiographers.
   c. **Patient Related Concerns:** The design must allow for controlled injections to patients, prevent air bubbles from being injected, prevent blood from flowing back up into the manifold and contaminating fluid, and must be ergonomic so that inexperienced operators may be able to correctly use the device.
   d. **Competition:** The Avanta Fluid Management Injection System made by Medrad performs many of the functions intended for this device, but is expensive and not widely used. There are very few other devices that combine the use of the manifold fluid management system and the ease of use of the power injector in the manner this device is intended for.