Heart phantom for testing of MRI guided catheter intervention

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ABSTRACT

A recently developed intravenous catheter aims to treat atrial fibrillation under MRI guidance. This device should effectively eliminate the patient's exposure to X-ray radiation during a traditional intravenous catheterization procedure. The heart phantom design described in this paper provides an adequate testing environment for the catheter before animal trials. The dimensions of the phantom's outer casing fit tightly inside a 13'' diameter cylindrical coil. The inner contents of the phantom mimic the physiological passage of the catheter into the atria. This internal vasculature was created using flexible and braided tubing, polycarbonate tube inserts and snap grip clamps. Two acrylic hemispheres were combined to resemble the atrial chambers of the heart. An acrylic square with holes of various sizes will allow for high resolution testing in the vicinity of the catheter tip. Initial MRI testing demonstrated that the phantom is completely MRI compatible and is sufficient for testing the catheter under real time MRI imaging.

INTRODUCTION

Atrial fibrillation is a condition characterized by irregular beating of the atria caused by disordered electrical signals within the atria of the heart. Atrial fibrillation may lead to numerous serious complications including poor blood flow, shortness of breath, fatigue, lightheadedness, heart palpitations, and chest pain. It may also lead to an increased risk of blood clots that form due to the pooling of blood in the atria when the heart beats out of sync, increasing the risk of stroke. Additionally, the wear caused by irregular beating may lead to heart failure.[1]

Possible treatment options for atrial fibrillation generally attempt to either reset the rhythm of the heart or disrupt the irregular electrical signals.[1] This can be accomplished with rhythm-controlling drugs or, if those fail to work, surgery. Treatments involving catheter intervention begin with the insertion of a catheter into the femoral vein at the groin (*Figure 1*). The catheter is then guided through the vasculature and into the left atrium of the heart. Once in place, the catheter may be used to scar the heart tissue surrounding the pulmonary veins via ablation. The pattern of scarring disrupts the erratic electrical signals originating in the pulmonary veins, and prevents further atrial fibrillation.[1]

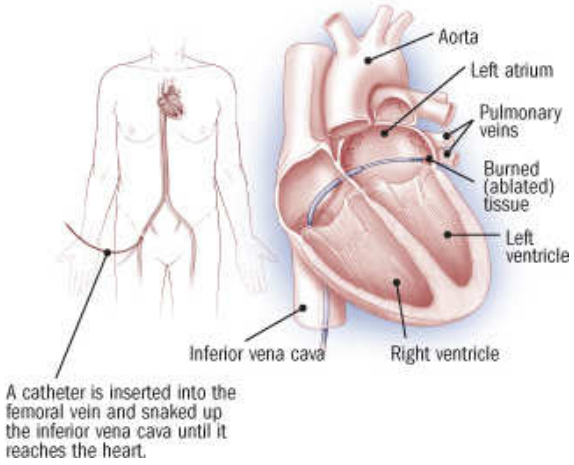

Figure 1: Catheter being used for ablation[2].

Performing this procedure under MRI guidance would eliminate a patient's exposure to harmful X-rays. To accomplish this, a catheter has been developed with a solenoid tip (tracking coil) that can be imaged with MR. This tip allows for the exact location of the catheter to be tracked. The catheter is imaged via two imaging coils: one near the tip of the catheter (catheter imaging coil) and one surrounding the phantom or patient (large imaging coil).

The heart phantom developed will be used in the initial testing of this new catheter before animal trials. The inner contents of the phantom must mimic the physiological passage of the catheter into the atria, containing the two atrial chambers, the four pulmonary veins, and the inferior and superior vena cava. The phantom also includes a high resolution block to test the imaging resolution of the smaller imaging coil at the tip of the catheter.

DEVICE DESIGN, FABRICATION, AND COST

A. Design Specifications

The heart phantom was to be designed to fit inside a cylindrical imaging coil of length and diameter both equal to 13". An external pump (not to be included in the device) would carry a saline solution through an inlet vessel, into the heart, and out through an outlet vessel. The four pulmonary veins would serve as the inlet vessels and would have an inner diameter (ID) between 0.39" and 0.79". The outlet vessel and catheter entry point would represent the superior and inferior vena cava respectively. The ID for these vessels would be between 0.79" and 1.18". The vasculature connects to a spherical casing with a 3" diameter representing the two atrial chambers of the heart. A thin membrane separating the two chambers would be mounted inside the casing and represent the septum between the right and left atrial chambers. Finally, all parts of the phantom were to be MRI compatible, completely leak proof, and transparent.

B. Materials and Methods

The phantom has square acrylic side panels 12" long and ½" thick with circular acrylic end caps 12" in diameter and ¼" thick, which together form the casing of the phantom. The top of the casing is attached with plastic screws for easy removal so that the case can be opened and the parts cleaned or replaced. The rest of the casing is held together with acrylic glue and sealed with silicon calk to make it completely leak proof.

In one of the end caps of the casing, a 1" diameter hole was drilled for the inferior vena cava and catheter entry point. Another ½" diameter hole was drilled on this same side to serve as a drain for any fluids in the phantom casing. In the other acrylic end cap, a 1" diameter hole was drilled for the superior vena cava, the outlet for fluid flow. Four ½" diameter holes were drilled on this same side for the four pulmonary veins, inlets for fluid flow (*Figure 2*).

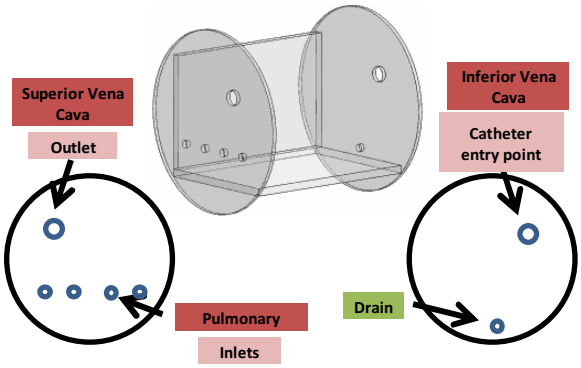

Figure 2: Casing with vessel inlet and outlet locations.

Stiff polycarbonate tubing was inserted through the acrylic wall to connect the flexible tubing on either side. The polycarbonate tubes were sealed in place with acrylic glue and silicon calk. At the catheter entry and outlet holes, the polycarbonate tubing has a 1" outer diameter (OD) while at the inlet holes it has a ½" OD. The polycarbonate tubing at the catheter entry point is tapered to prevent the catheter from catching as it travels from the flexible tubing to the polycarbonate tubing. The OD of the polycarbonate tubes matches the ID of the flexible tubing, allowing for a tight fit. On both sides of the polycarbonate tubing, the flexible tubing is sealed into place with snap grip clamps. These clamps ensure that the stiff and flexible tubing fit together without any leaks (*Figure 3*).

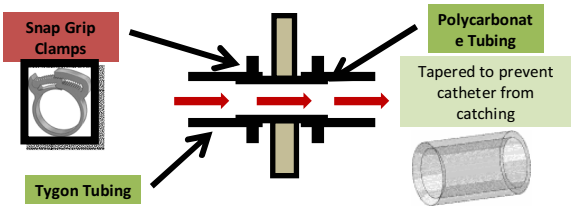

Figure 3: Through-wall tubing connections.

The flexible tubing used for the pulmonary veins and inferior vena cava is braid-reinforced tygon tubing that is more rigid than standard tygon tubing and therefore

less prone to kinking (*Figure 4*). The inferior vena cava has a 1" ID and 1 3/8" OD and the pulmonary veins have a ½" ID and ¾" OD.

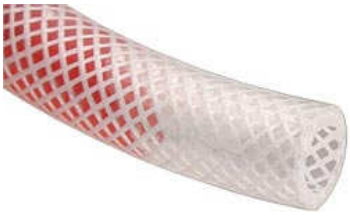

Figure 4: Braid-reinforced tygon tubing.

The flexible tubing used for the superior vena cava is standard tygon tubing with a 1" ID and 1¼" OD. This softer tubing was chosen for the outlet tube in order to retain some flexibility in the vasculature of the phantom, allowing the parts to be more easily disconnected and replaced.

The flexible tubing for the external vasculature, located outside the casing, is standard tygon tubing. The external tubing for the superior and inferior vena cava has a 1" ID and a 1 ¼" OD. The external tubing for the pulmonary veins has a ½" ID and a 5/8" OD.

The atrial chambers are represented by two 3" ID acrylic hemispheres with 1" flanges. The two sides of the heart are connected with plastic screws that go through the flanges in both halves and are secured with plastic nuts. The heart is sealed together with o-rings on the inside and outside of the screws and caulked to ensure that it is completely leak-proof. The right atrium has two 1" diameter holes for the superior and inferior vena cava. The left atrium has four ½" diameter holes for the pulmonary veins (*Figure 5*). Stiff polycarbonate tubing goes through the holes of the heart and connects to the flexible tubing on the outside. The flexible tubing is then secured to the polycarbonate tubing with snap grip clamps.

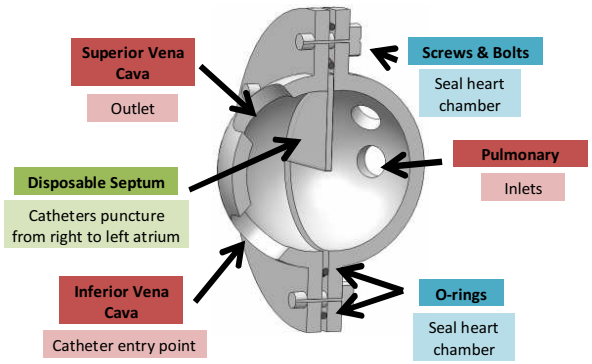

Figure 5: Heart chamber.

The external pulmonary veins attach to a manifold, which serves as a pathway for fluid entry into the system. The manifold connects to the pump via a quick-disconnect attachment. A sheath for catheter entry is attached onto a barbed reducer, which is attached to the external portion of the inferior vena cava. Lastly, the external portion of the superior vena cava is connected to a quick-disconnect that attaches to the outlet side of the fluid pump (*Figure 6*).

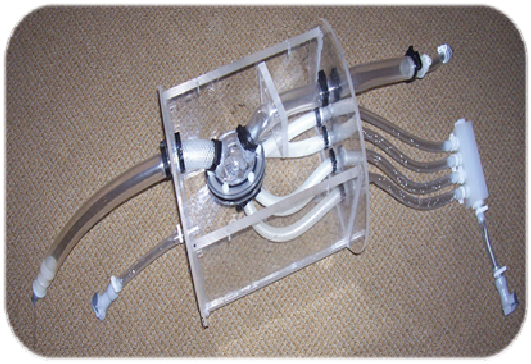

Figure 6: Final prototype with external connections.

A final component incorporated into the phantom is an acrylic block that will be used for high resolution testing of the catheter. The block has one large 1 ¼" diameter hole that the superior vena cava passes through. It also has four sets of two different sized holes to simulate the small vasculature surrounding the superior vena cava (*Figure 7*). The catheter will be placed in the superior vena cava within the center of the acrylic block and an MR

image will be taken. The resolution will be determined based on the image obtained of the holes in the acrylic block under MR.

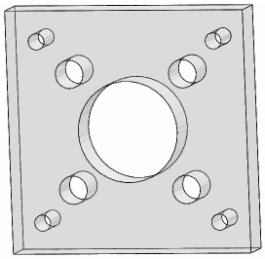

Figure 7: High resolution block.

C. Costs

After the phantom was completely constructed, the total costs came to $515.59 (*Table 1*).

Component	Part	Cost
Casing	Acrylic Sheets, 1/2" thick	$98.40
	Acrylic Circles, 1/4" thick	$37.76
Tubing	Braid-reinforced tygon tubing, 1" ID	$29.00
	Braid-reinforced tygon tubing, 1/2" ID	$32.50
	Tygon tubing 1" ID	$26.22
	Tygon tubing 1/2" ID	$14.20
Tube Fittings	1/2" OD Manifold fittings	$17.90
Pump Connections	Other	$52.37
	Quick-Disconnects	$44.24
	Manifold, 4 outlets	$42.75
	Barbed tube fittings	$14.42
Heart	Other	$27.83
	Acrylic hemispheres	$78.00
Total		**$515.59**

Table 1: Phantom material costs.

TESTING AND RESULTS

Initial testing was conducted on the device to ensure no leakage occurred, either from the casing or the vasculature. The casing was filled with water, which revealed no leaks. The tubing was then tested by filling the entire circuit with water in a static state. The phantom was then connected to a pump to ensure that no leaking occurred during a constant flow.

Once the device was determined to be leak-proof, MRI testing was conducted. The casing was filled with water for loading purposes, and then the tubing was filled via the pump. Once filled, the solenoid-tipped catheter was inserted into the device through the sheath and maneuvered until it reached the heart. Several MR images were obtained by the catheter imaging coil and the large imaging coil.

The large imaging coil surrounding the phantom provided a large field of view. In this image the tracking coil on the catheter was visible, but only showed up faintly. The phantom itself, however, was clearly revealed. The catheter imaging coil was able to generate a small and bright white spot on the image for the tracking coil. However, the phantom structures were faint and only visible in the immediate vicinity of the catheter tip. This smaller range was due to the small field of view of the catheter imaging coil. However, this image had a greater resolution and SNR compared to the large imaging coil. By superimposing the images obtained from the two imaging coils, an image clearly revealing the location of the catheter with respect to the phantom was obtained (*Figure 8*).

The catheter was also tracked in real time during the testing. This was accomplished using a program that was able to display a red dot at the current location of the tracking coil, which corresponds to the catheter tip. Smaller dots were seen where the catheter tip had previously been located. The heart phantom was used successfully in a test of the real-time catheter tracking.

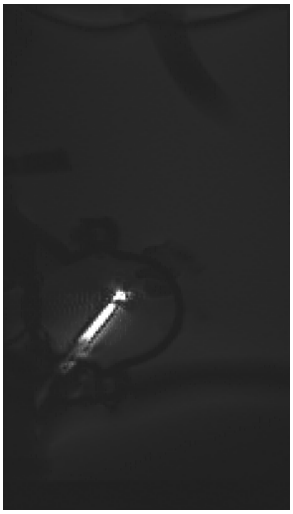

Figure 8: MRI image of tracking coil at tip and catheter imaging coil with superimposed images from both imaging coils.

DISCUSSION

The phantom's final design fulfilled all of the design requirements and was successfully tested under the conditions required for use. The device fits inside the 13" diameter coil used for testing, is MRI compatible, and transparent. Fluid flows quickly and evenly through the phantom with no leaks or bubbles. The phantom also incorporates a heart and the major vasculature needed for testing purposes. Nearly all parts of the phantom can be removed and replaced as necessary.

The catheter was successfully maneuvered through the inferior vena cava and into the heart chamber of the phantom. MR images from both imaging coils were taken and superimposed, resulting in an image containing both the tracking coil (catheter tip), imaging coil, and surrounding vasculature.

One improvement in the future involves eliminating the need for caulk to seal the heart chamber. Using only the o-rings to seal the heart, the phantom experienced a great deal of leaking. As a result, the two halves of the heart had to be caulked together and will need to be re-caulked each time the two halves are separated. In order to remedy this in the future, o-rings of a softer, better sealing material will need to be purchased and implemented into the phantom.

CONCLUSION

The testing results indicated that the phantom successfully fulfilled the initial requirements for the MRI guided testing of the catheter. The phantom was nonferrous and leak-proof to satisfy the MRI compatibility while inside the magnet. The photos and videos captured for the catheter maneuvers inside the phantom demonstrated that the position of the catheter tip was effectively tracked by MR imaging. With the incorporation of the software available, close to real time imaging has become possible so that the user will receive visual feedback for the current location of the catheter. In the future, the phantom will be used extensively to test how accurately a user can maneuver the catheter under MRI through winding vasculatures before arriving at the atria.

REFERENCES

[1] Mayo Clinic Staff (2007) Heart Disease: Atrial Fibrillation. Retrieved October, 2008, from http://www.mayoclinic.com/health/atrial-fibrillation/DS00291

[2] Harvard Medical School Faculty (2006) Atrial Fibrillation: Beyond Drug Therapies. Retrieved December, 2008, from http://www.aolhealth.com/conditions/atrial-fibrillation-beyond-drug-therapies

APPENDIX - PDS

Heart Phantom PDS
(May 7th, 2009)

Client: Orhan Unal, Ph.D.
Advisor: Willis Tompkins, Ph.D.
Team Members: Erin Main (Co-Team Leader)
Jessica Hause (Co-Team Leader)
Lacey Halfen (Communications)
Peter Strohm (BSAC)
Fan Wu (BWIG)

Function: A heart phantom will need to be designed to be used for the initial testing of a solenoid tipped catheter in order to gain FDA approval. The catheter will ultimately be used to treat atrial fibrillation under MRI guidance. The transparent phantom will have vasculature mimicking the superior vena cava, the inferior vena cava and the four pulmonary veins. The heart will consist solely of the two atrial chambers separated by a disposable septum. The vasculature and heart will need to be filled with a saline solution in both a static and dynamic state without the risk of leaking. The phantom will ultimately be used to test the maneuverability of the catheter under MRI guidance as well as high resolution imaging capabilities in the vicinity of the solenoid tip.

Client Requirements:

- Casing
  - Fit inside a cylinder with a length and diameter of 13''
  - Drain attachment to empty fluid in casing
- Vasculature
  - Superior and inferior vena cava with diameter between 20 – 30 mm (0.75 - 1.25 inches)
  - Pulmonary veins with diameter between 10 – 20 mm (0.4 – 0.75 inches)
  - Superior vena cava functions as the outlet for the system
  - Inferior vena cava functions as catheter entry point and will be statically filled with fluid
  - Pulmonary veins function as the inlets to the system
- Heart chamber
  - Left and right atrium separated by a thin disposable septum
  - Superior and inferior vena cava terminate in right atrium
  - Pulmonary veins terminate in left atrium
- General
  - Leak proof
  - No ferrous material
  - Transparent

Design Requirements:

1. Physical and Operational Characteristics

a. *Performance requirements*: The device will be used on a weekly basis under MRI. All parts should be capable of being removed and replaced as necessary. The heart should be able to be taken apart for insertion or removal of the disposable septum.

b. *Safety*: The heart phantom must be completely leak proof and lack ferrous materials so as to avoid a negative interaction with the MRI machine and prevent damage.

c. *Life in Service*: Our device should have a minimum lifespan of five years with internal vasculature and septum being replaced as necessary.

d. *Shelf Life*: The heart phantom will be stored at room temperature when not in use.

e. *Operating Environment*: The device will operate inside an MRI scanner while a saline solution or water is pumped through the vasculature. The casing will either be filled with water or an agarose gel for weighting purposes. The internal vasculature will be under pressure while fluid is being pumped though the circuit.

f. *Size*: The product will need to fit into a cylinder that has a length and diameter both equal to 13 inches. The internal vasculature will need to have diameter between 20 and 30 mm for the superior and inferior vena cava and between 10 and 20 mm for the pulmonary veins. The heart chamber will need to be approximately 3 inches in diameter. The device will also need to have an access area on the top so that tubing and the disposable septum can be changed on a regular basis.

g. *Weight*: The product should weigh no more than 20 lbs. when completely filled with saline or water so that one individual can easily move the phantom on and off the MRI table.

h. *Materials*: No corrosive or ferrous materials as this device will come in contact with fluids on a regular basis and be used in MRI scanners.

i. *Aesthetics, Appearance, and Finish*: The device should be completely transparent. The casing should be cylindrical in shape to mirror the shape of the cylindrical MRI coil and to maximize the internal space available for vasculature. The heart chamber should resemble the actual human heart as much as possible. The location of the pulmonary veins in the left atrium should be accurate, since this is the portion of the heart where the ablation procedure is performed.

2. Production Characteristics

a. *Quantity*: 1

b. *Target Product Cost*: Under $1,000.