Cooling Device for Transesophageal Ultrasound

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Abstract.

The purpose of this design was to create a cooling device for a Philips X7-2T 3D transesophageal ultrasound probe. The device should be small enough to fit into the esophagus of a swine model when attached to the probe, and should keep the internal probe temperature at a steady state value below 42 degrees Celsius. A prototype of this device was fabricated using vinyl tubing, low-density polyethylene (LDPE) and Tygon tubing, and was tested both in vitro and in vivo. The prototype successfully held the internal probe temperature below 42 degrees Celsius in each test and kept the temperature at a steady state value during in vitro testing. However, the size of the device was larger than specified when an additional EM tracking device was attached to the probe tip, and it was difficult to obtain a completely watertight seal on our prototype.

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Problem Statement

Our client has been using a prototype of a new 3-D transesophageal ultrasound probe in pigs to image an injection catheter in the left ventricle. The injection catheter and imaging method are being tested as a method to deliver stem cells to damaged heart tissue. The continuous imaging that is required to determine the placement of the injection catheter and the stem cells causes the probe to overheat and turn off until it has cooled down enough to prevent any tissue damage. Our client would like a device to cool the ultrasound probe so that he could image for a longer period of time without tissue damage. This project would have commercial potential, as this is a novel use of 3-D ultrasound. The cooling device could be as simple as using cold saline to flush the probe to a more sophisticated electronic cooling device.

Background

Heart Disease

Tim Hacker and Amish Raval of the UW Department of Medicine are conducting research to determine to what extent stem cells can regenerate dead heart tissue. The American Heart Association reports that there are 1,260,000 new and recurrent coronary attacks occur per year. About 37% of people who experience a coronary attack in a given year die from it (Heart Attack and Angina Statistics). Additionally, an estimated 5.7 million Americans live with heart failure with 670,000 new cases diagnosed each year (Heart Attack and Angina Statistics). By creating a method where tissue in the heart could be regenerated, many of these cases could be better treated. A heart attack occurs when blood flow is blocked and the myocardial tissue gets starved of blood. Without oxygen from the blood, myocardial cells die and the muscle tissue can become permanently damaged without treatment. The goal of this research is to discover if direct injection of mesenchymal stem cells isolated from bone marrow can be effectively injected into

dead heart tissue, and if so, how these cells could be used to treat cardiovascular disease. Mesenchymal bone marrow cells are able to differentiate into myocardial cells and show great promise for heart tissue regeneration (Wu). Hope is that this treatment will be able to regenerate dead heart tissue caused by heart attacks in a minimally invasive manner.

For a typical procedure, our client begins by inducing heart attacks in swine models, which creates regions of dead tissue in the heart. He then enters the left ventricle of the heart with a single injection catheter via the femoral artery. The current catheter used is the Myostar made by Biosense-Webster (see figure 1). This catheter incorporates a retractable needle tip and exhibits a single degree of freedom.

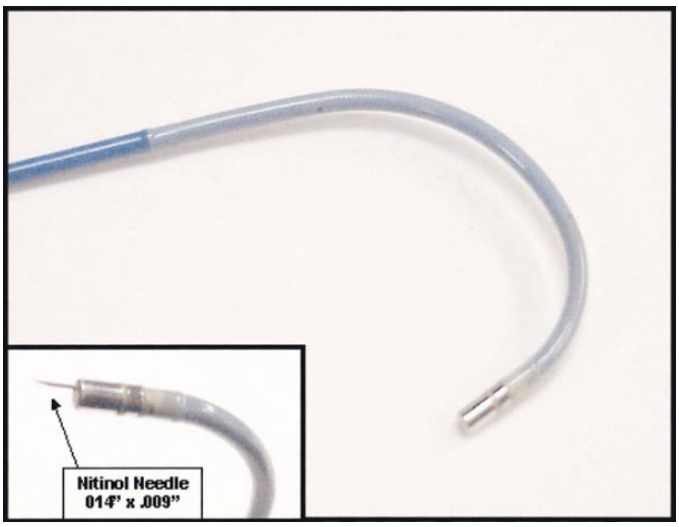

Figure 1: The Myostar injection catheter made by Biosense Webster currently being used by the client (Callans et al).

During this process he utilizes ultrasound imaging to determine the location of the catheter in the heart. He then determines his location based on ultrasound and injects the stem cells into the region of cell death. However, each procedure using the Myostar catheter is very time consuming, and the area of dead myocardial tissue is often large which requires numerous

injections. In addition, the Myostar catheter must be repositioned for each injection, which is extremely difficult. With only one degree of freedom, it is hard for our client to position the tip of the catheter accurately, and during the procedure the heart remains beating, which adds to the difficulty. Due to the long duration of the procedure, our client has experienced problems while obtaining continuous images because, due to a safety mechanism, the ultrasound machine shuts off when the internal probe temperature reaches 42.5 degrees Celsius. To solve this problem, our client has created a simple device that consists of a catheter that is attached to the ultrasound probe by surgical tape that drips cold saline onto the tip of the ultrasound probe. The cold saline cools the ultrasound device to keep it at a steady state temperature. The device is an open loop system, thus, the saline drips off the ultrasound probe and into the swine's stomach. Our client looks for a device that can be to attached to the end of the probe and cool the device so he is able to image for extended periods of time without the ultrasound machine turning off.

Ultrasound Imaging

During the procedure performed by out client, 3D transesophageal ultrasound imaging is utilized to determine the location of injections. For this imaging, our client uses a Philips X7-2T ultrasound probe, shown in Figure 2. Transesophageal ultrasound imaging utilizes an ultrasound transducer placed on an endoscope. The endoscope can be inserted through the mouth and into the esophagus, and in this location the ultrasound transducer will produce high frequency sound waves that reflect off the tissue to be recorded to produce images of the heart that are called an echocardiogram. (Transesophageal Echocardiogram). With the Philips X7-2T, our client is able to get live 3D images of the heart during the entire procedure. However, because the X7-2T

utilizes new technology to obtain these 3D images, it has the potential to heat up and shut down because the technology has yet to be perfected.

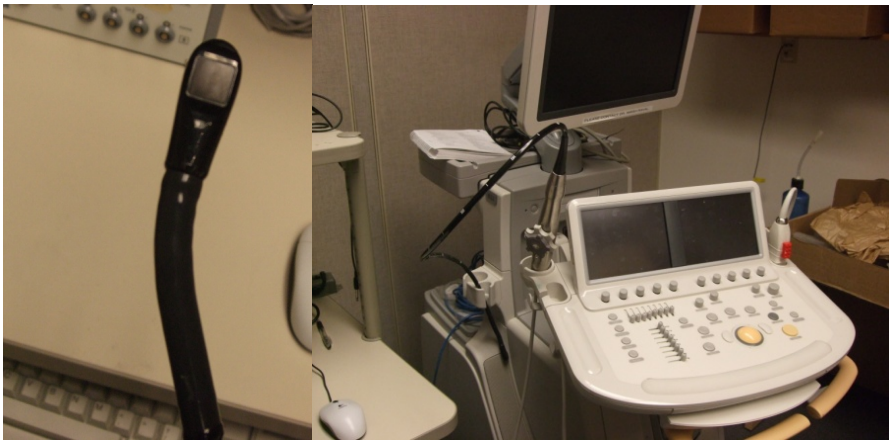

Figure 2: Philips X7-2T ultrasound probe and accompanying ultrasound machine. Image taken February 1st, 2010.

Design Specifications

The design requirements were obtained by discussions with our client about his wants and needs for a cooling device prototype.

The primary physical requirement is that the device should be able to keep the ultra sound probe at a steady state temperature under 42 degrees Celsius. The device though should keep the probe within a range of 10-42 degrees Celsius. The shape of the device should not interfere with the esophagus during insertion. Thus, it should not protrude more than 1 cm total from the device (no more than 0.5 cm on each side). In addition, the device should also be smooth so it does not cause damage to the esophagus when being inserted. Materials used should be able to withstand acid and chemicals from the pig's esophagus and should not interfere with imaging. The weight of the device should be minimized (at least under 5lbs) so it is non-cumbersome to the user.

With regards to the service life of the device, it should be able to withstand frequent use in a controlled clinical environment. The device needs to fit in the client's current set up and thus extraneous parts (tubing, wires, etc.) should be minimized to ensure and organized and safe environment for testing.

Design Alternatives

To provide our client with a prototype that met his specifications, three initial designs were developed. Each design utilizes fluid cooling to keep the temperature of the probe at a steady state value, and each is to be externally attached to the tip of the probe.

1. Liquid Tubing

Overview

The first of three designs involves plastic tubing wrapped around the probe through which a cool liquid such as saline would flow. This closed loop design would consist of a continuous section of tubing connected to saline bags on each end. To start the cooling, one of the saline bags would be full and the other empty. Gravity would cause the cool saline flow from the first bag, through the tube, and to the end of the probe where it would drain into the empty bag. The flowing water would surround the end of the probe and cool it as seen in Figure 3. Both bags would be located outside of the animal and could be manipulated by the client if adjustments in flow rate were needed. This device would be fastened to the animal by surgical tape or a

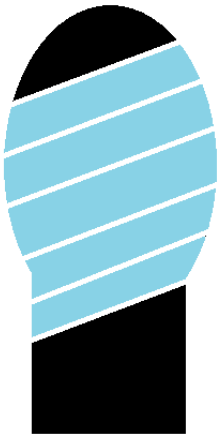

Figure 3: Drawing of liquid tubing design. The tubing will be wrapped around the tip and saline will flow through the tubing.

similar adhesive.

Advantages and Disadvantages

An advantage of this design is that it is low-cost because it consists only of plastic tubing and saline bags. It is also safe to manufacture. However, this design may be more difficult to attach to the probe than the others. Unlike some of our designs, this one would likely require more than one person to assemble. Assembly would also be difficult because the plastic tubing could easily interfere with the piezoelectric crystal, a crystal that emits sound waves essential for creating the image. Wrapping the tubing in a way that avoids the piezoelectric crystal would be time consuming and challenging.

2. Gas Cooling

Overview

The second proposed design is the same as the first except for the cooling agent. In the second design, gas would be used in place of saline. Gas would have a cooling effect on the end of the probe because it would expand when released into the tubing, and gas cools as it expands. Most hospital rooms contain gas outlets so the cooling agent would be readily available.

Advantages and Disadvantages

This design would be more complex to manufacture than the others because connectors and converters would be needed to connect the tubing to wall outlets. This design also presents a significant safety concern. Should the tubing puncture while inside an animal, its effect would be dangerous and potentially fatal.

3. Liquid Reservoir

Overview

The third proposed design uses a liquid reservoir. Like the first design, this one would use saline as a cooling agent in a closed loop system. Two saline bags would be connected to the tubing from which the flow of saline would be controlled by gravity. Unlike the first design, however, the tubing in this design would not be wrapped around the probe. Instead, it would be connected directly to a liquid reservoir that would be attached to the tip of the probe. Saline would flow into the reservoir and circulate within it before draining to an output (i.e. empty saline bag).

Advantages and Disadvantages

This design would be easier than the others to attach to the probe and could be easily removed. By covering the entire backside of the probe, this design will provide adequate cooling while avoiding disruption of the piezoelectric crystal. Like the other designs, this one would be attached to the animal by surgical tape or a similar adhesive.

Design Decision

	Cost (0.05)	Cooling (0.30)	Ease of use (0.30)	Safety (0.15)	Ease of Manufacturing (0.20)	Total
#1 Gas	7 (0.35)	4 (1.2)	5 (1.5)	3 (0.45)	4 (0.8)	4.3
#2 Tubing	10 (0.5)	7 (2.1)	7 (2.1)	10 (1.5)	9 (1.8)	8.0
#3 Reservoir	8 (0.4)	10 (3.0)	9 (2.7)	10 (1.5)	7 (1.4)	9.0

Figure 4: Design matrix showing weights of each factor and scores for our three alternative designs.

After coming up with three design proposals, our team created a design matrix to aid in choosing the best design. We chose to weigh five factors in this matrix, including cost, cooling efficiency, ease of use, safety and ease of manufacturing. We decided that cost would be given the least weight (0.05) because it is the least important factor. This is because we have a sufficient budget, and the functionality of our cooling device is much more important than its cost. Safety, a more important factor, was given a weight of 0.15. Some of our designs present more safety risks than others, and this must be considered when choosing the best design. Ease of manufacturing was given a weight of 0.20 because it is essential that our device be easy to fabricate. Finally, we deemed cooling and ease of use the two most important factors in our design. These factors were both given a weight of 0.30.

As seen in Figure 4, the gas tubing design received the lowest score in our design matrix. This design has a number of issues that keep it from being a feasible option. The first issue is related to safety; working with gas cylinders and gas expansion is more dangerous than using liquid as a cooling agent. Another problem with this design is that it would be more difficult to fabricate than the others. Unlike the other designs, this one requires converters to connect the gas cylinder to the tubing. It also requires construction of a custom plastic tube to serve as an expansion chamber. Additionally, this device would not be portable with the ultrasound machine due to the need for gas cylinders. Finally, we believe that gas would be a less effective cooling agent than liquid. Gas interferes with ultrasound imaging, and we would therefore be able to cool only the back of the ultrasound probe.

The liquid tubing design scored substantially better than the gas tubing design. This was mainly due to better safety, ease of use, ease of manufacturing and cooling efficiency. The most beneficial part of the liquid tubing design is that we would not need to construct an actual device. We would only need tubing and with saline bags. We would then design the most efficient and simple method of wrapping the tubing around the probe to provide the necessary cooling effect.

The reservoir design scored the best in our design matrix. It was comparable to the liquid tubing design in most categories but scored better in cooling efficiency and ease of use. We believe that the reservoir design would have greater cooling ability than the tubing design because it would have a larger area that is in contact with the probe. This should allow for more heat to be carried away from the probe by the saline. The reservoir design would also be easier to use because it will take less time to attach it to the probe. The tubing design would require extensive wrapping of the tube around the probe while the reservoir design would only require strapping or taping the reservoir to the probe. The only drawback of the reservoir designs is that it would be more difficult to construct than the tubing design.

Final Design

Revised Design

After the mid-semester presentations we revised our reservoir design. We decided against using half of a tube for support in the reservoir. We did this because we were concerned about the inner tube not providing enough support to allow for saline flow while the device was attached to the probe. As a result we decided to use smaller pieces of tubing placed inside of the reservoir

that would provide more support while still allowing for the flow of saline. We chose polyethylene film and Tygon tubing as our materials for this design.

Construction of Revised Design

Our plan for constructing the device consisted of gluing pieces of Tygon tubing to a piece of polyethylene film (4 cm width and 4 cm length). We would then glue the longer inlet and outlet tubes to the middle and outer edge of the film. Next, we would fold the polyethylene film down the middle and heat seal the bottom, top, and outer edges. This would create a pouch (2 cm width and 4 cm length) that is supported in the middle while still allowing for a flow of saline that would cool the ultrasound probe.

Construction of our revised design was very difficult. The main problem arose in trying to glue the Tygon tubing to the polyethylene film. We tried using medical epoxy, 5-minute epoxy, multiple kinds of superglue, hot glue, rubber cement and polyurethane glue, but none of these would sufficiently attach the Tygon tubing to the polyethylene film. As a result we decided to revert back and construct our initial reservoir design.

Final Design Construction

Our final design's materials include polyvinyl tubing, Tygon tubing, and polyethylene film. This design consists of the polyvinyl tubing inside of the polyethylene film. The Tygon is used for the inlet and outlet tubing. The dimensions of this cooling device are 1.5 cm height, 1.5 cm width, and 4 cm length. These dimensions are also shown in Figure 5.

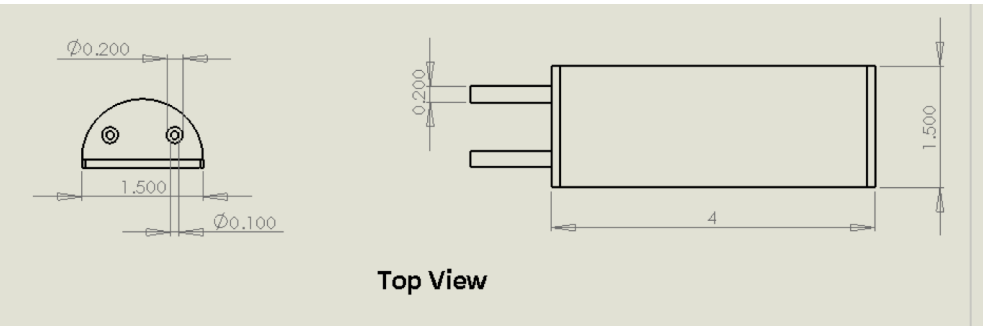

Figure 5: Dimensions of prototype as shown in a Solidworks representation

To construct this device we used a polyethylene spray adhesive. First we attached the long inlet and outlet tubes to a piece of polyethylene film using the spray adhesive. We then cut the polyvinyl tubing in half and attached it to the polyethylene film using the spray adhesive. Polyethylene film was then wrapped around the polyvinyl tubing multiple times, encasing the Tygon and polyvinyl tubing in polyethylene film. The spray adhesive was used in between each layer of polyethylene film as it was wrapped. Adhesive was also used to close and seal the top of the device near the inlet and outlet tubes.

Figure 6 shows one of our constructed cooling devices. The multiple layers of polyethylene provide greater durability, while the polyvinyl tubing provides support when our device is attached to the ultrasound probe.

Figure 6: Constructed cooling device.

Attaching our cooling device to the ultrasound probe will be done using surgical tape. Our cooling device will be placed against the backside of the probe (so that it does not interfere with the ultrasound imaging), and surgical tape will then be wrapped completely around the device to ensure secure attachment. Gravity will be used to create flow through our cooling device. One cool bag of saline will be connected to the inlet Tygon tubing and hung from an IV stand, and one empty bag will be attached to the outlet Tygon tubing and placed at the bottom of the ultrasound machine. This will cause the cool saline from the full bag to flow through our device and into the empty bag while carrying heat away from the ultrasound probe.

Testing

In vivo and in vitro testing was performed to see the effects of our prototype on probe temperature. Initially, in vitro control tests were performed to obtain temperature data from the probe when it is without a cooling device. For this testing, we used a container filled with beef to simulate tissue. A water bath kept at 37°C surrounded the container to keep the tissue near body temperature. The probe was placed in the container, turned on, and internal temperature measurements were taken from the probe every 30 seconds. On the ultrasound machine, it was possible to set various patient temperatures, affecting the temperature response of the probe. The above procedure was repeated for three of these set patient temperatures: 37, 39, and 41°C. Temperature vs. time graphs from this testing can be seen in Figures 7a, 7b, and 7c. As shown in these graphs, increasing the patient temperature increases the probe's rate of temperature increase, causing it to shutdown more quickly. With this in mind, it is suggested that the patient

temperature should be set to 37 degrees Celsius whenever possible to minimize temperature increase.

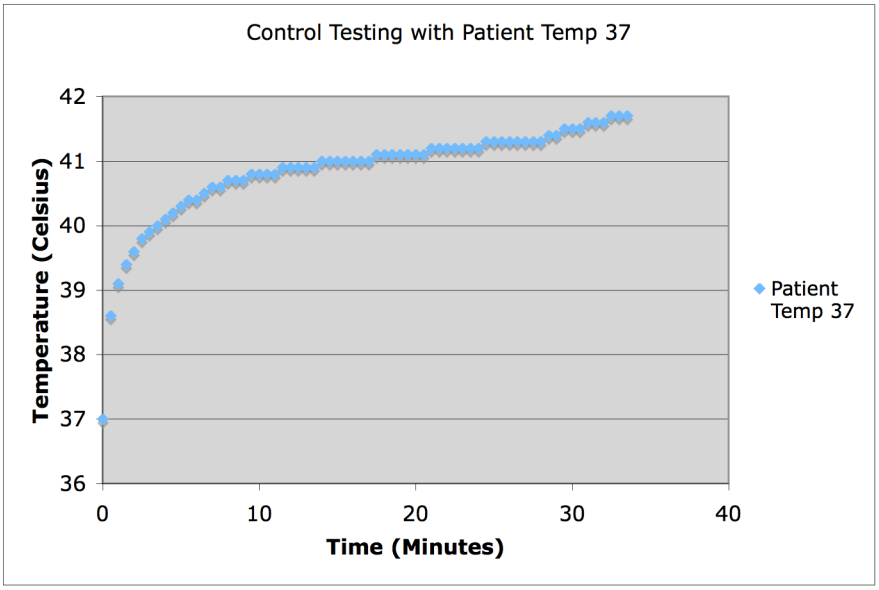

Figure 7a: In vitro control testing data at a patient temperature of 37°C. Tables of testing measurements can be found in Appendix B.

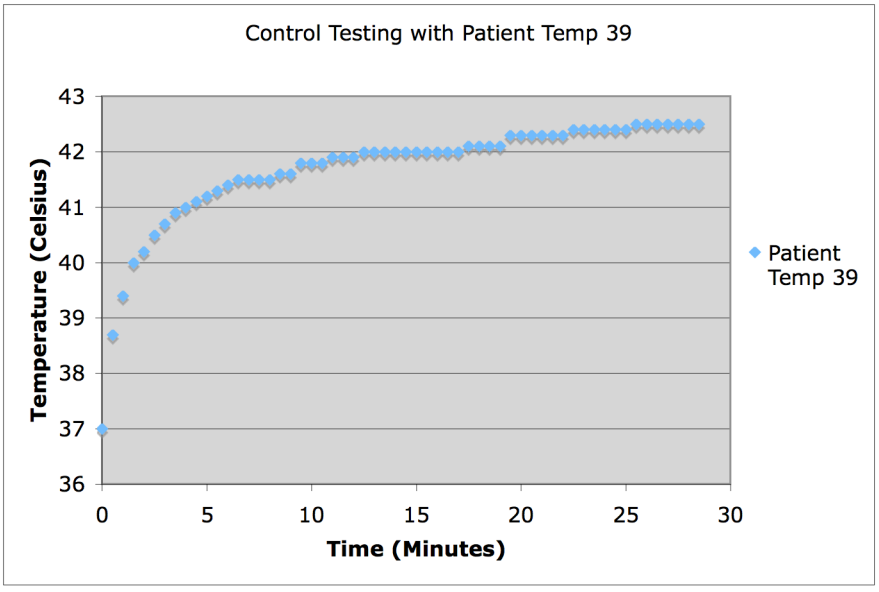

Figure 7b: In vitro control testing data at a patient temperature of 39°C. Tables of testing measurements can be found in Appendix B.

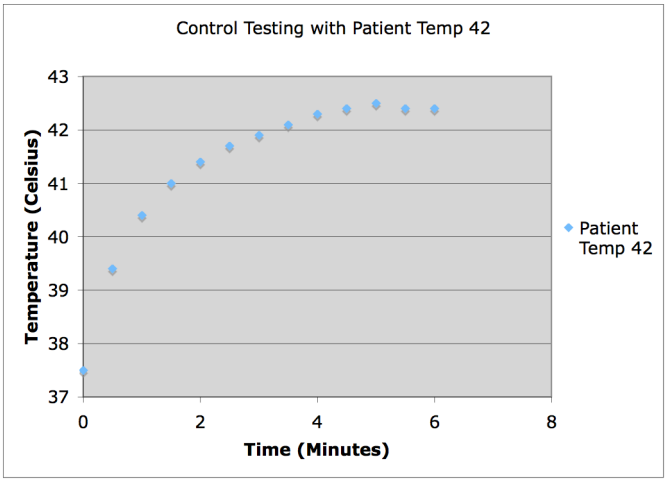

Figure 7c: In vitro control testing data at a patient temperature of 42°C. Tables of testing measurements can be found in Appendix B.

Later, these tests were repeated with a cooling device prototype. The same procedure as above was performed, but the cooling device was taped to the tip of the probe with room temperature saline running through it at various drip rates. Data for this in vitro testing is shown in Figure 8a and 8b. As shown in these figures, the device maintained a steady state of 39.2 degrees Celsius at a drip rate of 108 drips/min and of 40.1 degrees Celsius at a rate of 48 drips/min.

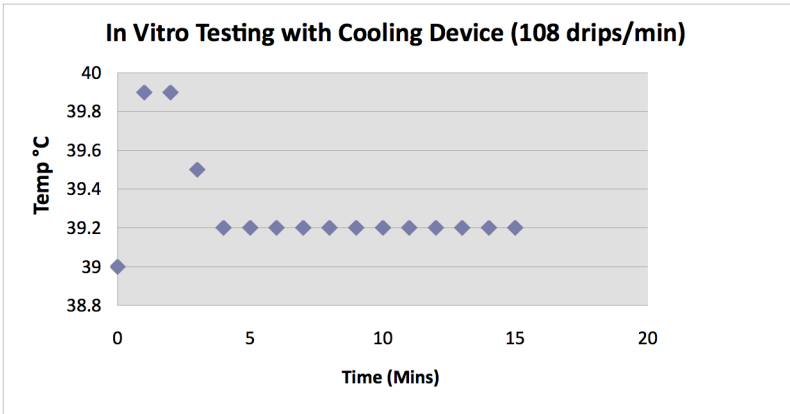

Figure 8a: In vitro testing data with cooling device at 108 drips/min with a probe set patient temperature of 39°C. Tables of testing measurements can be found in Appendix B.

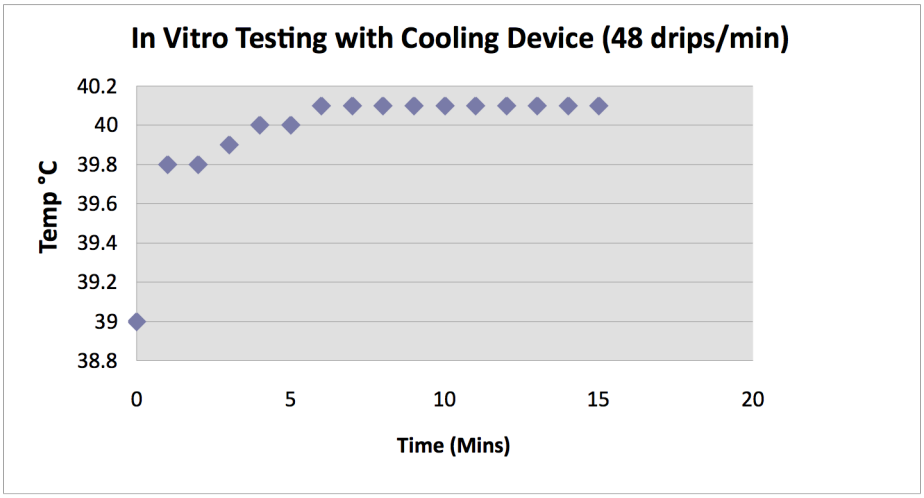

Figure 8b: In vitro testing data with cooling device at 48 drips/min with a probe set patient temperature of 39°C. Tables of testing measurements can be found in Appendix B.

Finally, we had the opportunity to perform in vivo testing with the device on a swine model. For this testing, we attached the cooling device to the probe with surgical tape and ran cold saline through it, varying the drip rates throughout the testing. As shown in Figure 9, the probe was kept below 42 degrees Celsius for the entirety of testing (up to 95 minutes). However, an additional EM tracking device was attached to the probe during testing, causing the probe tip to be larger than specified. Due to this, minor bleeding occurred during the procedure. In addition, minor saline leakage occurred as the prototype was not completely watertight after attachment to the probe tip. Nevertheless, the prototype manages to achieve its primary goal of keeping the probe below 42 degrees Celsius.

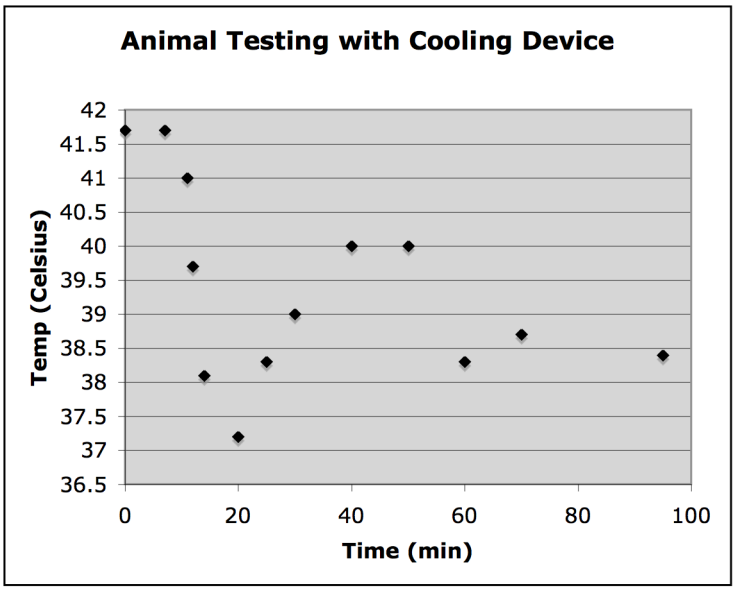

Figure 9: Animal testing with cooling device prototype. Tables of testing measurements can be found in Appendix B.

Future Work

Although our design successfully kept the probe at a steady state temperature, there are a few desirable improvements that could be made. First, most of the prototypes had minor leaks because the polyethylene spray adhesive does not strongly seal the LDPE around the tubing that enters and exits the reservoir. Solvent glues or other adhesives are unlikely to work for this due to the flexibility of both the tubing and LDPE and the chemical resistance of their surfaces. In the future, it would be desirable to have a seal that allows the user to manipulate the device without fear of leaking. Heat treatment is probably the best solution to this issue, and an open flame or other source of heat could be used to melt the LDPE to the tubing. An example of heat-treated LDPE bags can be seen in Figure 10.

Figure 10: Image of heat-treated low-density polyethylene bags from (Hot Melt Systems).

Another problem with our current prototype is that when attached to the probe and fully taped, it was a little bulky and rough. Initially, we designed our prototype for the probe alone, but when we actually performed testing an EM tracking device was attached to the probe tip as well, causing it to be bulkier than expected. In addition, the tape used to attach the cooling device to the probe tip was bulky and rough itself. Due to the size of the probe tip and the roughness of the tape, minor bleeding from the mouth occurred during the procedure. In the future we look to make a smaller model of our device to help solve this problem. In addition, we hope to find a better method of attachment that is smoother than surgical tape as well as easier to attach. With these modifications and a method for mass production, this design could potentially be produced as a disposable cooling device for ultrasound probes or other devices with cooling needs.

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Appendix A: Product Design Specifications (PDS)

Project: Cooling device for a transesophageal 3-D ultrasound probe (probe_cooling)

Team: Michael Conrardy – Team Leader
Joel Webb– Communications
Andrew Bertram – BWIG
David Leinweber – BSAC

Problem Statement:
Our client has been using a prototype of a new 3-D transesophageal ultrasound probe in pigs to image an injection catheter in the left ventricle. The injection catheter and imaging method are being tested as a method to deliver stem cells to damaged heart tissue. The continuous imaging that is required to determine the placement of the injection catheter and the stem cells causes the probe to overheat and turn off until it has cooled down enough to prevent any tissue damage. Our client would like a device to cool the ultrasound probe so that he could image for a longer period of time without tissue damage. This project would have commercial potential as this is a novel use of 3-D ultrasound. The cooling device could be as simple as using cold saline to flush the probe to a more sophisticated electronic cooling device.

Client Requirements:

• A continuous method of cooling the ultrasound probe

• Prevent probe from heating to 42 degrees Celsius where shutdown occurs

• Cool at a steady state temperature for up to 2 hours

• The cooling device must be waterproof

• The cooling device must withstand conditions in the esophagus

• Preferred the probe is not permanently attached to the probe

Design requirements:

Physical and Operational Requirements

a. *Performance Requirements* – The cooling device should be able to keep the probe at a steady state under 42 degrees Celsius for a minimum of two hours

b. *Safety* – The unit should not harm the animal in any way by being too bulky to be inserted

down the esophagus, by being to rough or by being toxic.

c. *Accuracy and Reliability* – The unit should keep the temperature of the probe within 10-42 degrees Celsius.

d. *Life in Service* – The unit should be able to withstand frequent use in a controlled, clinical environment for a long duration. It should be able to withstand conditions within the esophagus.

e. *Shelf Life* – The unit should not degrade while in storage.

f. *Operating Environment* – The unit should be able to withstand acid and chemicals in the esophagus of the pig. It must not be affected by the ultrasound imaging process.

g. *Ergonomics* – The unit should not interfere with the insertion of the probe into the esophagus. It should not protrude more than 1 cm total from the device (no more than 0.5 cm on each side if it surrounds the probe).

h. *Size* – The unit must be able to fit inside a pig's esophagus (see *g*).

i. *Weight* - The weight should be minimal (at least under 5 lbs).

j. *Materials* – Plastic is likely to be used. Materials should not interfere with ultrasound or kill the animal (no toxic chemicals).

k. *Aesthetics* – The unit should integrate well with the probe.

Product Characteristics

a. *Quantity* – Only one cooling device is required because the client only has one ultrasound probe.

b. *Target Product Cost* – Budget will be adequate for the manufacturing of these units, although cost should be kept under $150.

Miscellaneous

a. *Standards and Specifications* – The unit will fit within the client's current testing protocol, thus no further board approval is necessary.

b. *Customer* – It is okay if the animal is slightly harmed during the procedure, the primary goal is to keep the probe from shutting down.

c. *Patient-related concerns* – Not applicable

d. *Competition* – Other cooling devices exist but none made specifically for a 3-D transesophageal ultrasound probe

Appendix B: Table of data collected during in vitro and in vivo testing

Animal Testing Time (mins)	**Temp °C**
0	41.7
7	41.7
11	41
12	39.7
14	38.1
20	37.2
25	38.3
30	39
40	40
50	40
60	38.3
70	38.7
95	38.4

In Vitro Testing Time (mins)	**48 drops/min**	**108 drops/min**
	Temp °C	**Temp °C**
0	39	39
1	39.8	39.9
2	39.8	39.9
3	39.9	39.5
4	40	39.2
5	40	39.2
6	40.1	39.2
7	40.1	39.2
8	40.1	39.2
9	40.1	39.2
10	40.1	39.2
11	40.1	39.2
12	40.1	39.2
13	40.1	39.2
14	40.1	39.2
15	40.1	39.2

Control Testing	**Patient Temp 37°C**	**Patient Temp 39°C**	**Patient Temp 42°C**
Time (s)	Temp °C	Temp °C	Temp °C
0	37	37	37.5
30	38.6	38.7	39.4
60	39.1	39.4	40.4
90	39.4	40	41
120	39.6	40.2	41.4
150	39.8	40.5	41.7
180	39.9	40.7	41.9
210	40	40.9	42.1
240	40.1	41	42.3
270	40.2	41.1	42.4
300	40.3	41.2	42.5
330	40.4	41.3	Shutdown
360	40.4	41.4	
390	40.5	41.5	
420	40.6	41.5	
450	40.6	41.5	
480	40.7	41.5	
510	40.7	41.6	
540	40.7	41.6	
570	40.8	41.8	
600	40.8	41.8	
630	40.8	41.8	
660	40.8	41.9	
690	40.9	41.9	
720	40.9	41.9	
750	40.9	42	
780	40.9	42	
810	40.9	42	
840	41	42	
870	41	42	
900	41	42	
930	41	42	
960	41	42	
990	41	42	
1020	41	42	
1050	41.1	42.1	
1080	41.1	42.1	
1110	41.1	42.1	
1140	41.1	42.1	
1170	41.1	42.3	
1200	41.1	42.3	
1230	41.1	42.3	
1260	41.2	42.3	
1290	41.2	42.3	
1320	41.2	42.3	
1350	41.2	42.4	

1380	41.2	42.4
1410	41.2	42.4
1440	41.2	42.4
1470	41.3	42.4
1500	41.3	42.4
1530	41.3	42.5
1560	41.3	42.5
1590	41.3	42.5
1620	41.3	42.5
1650	41.3	42.5
1680	41.3	42.5
1710	41.4	42.5
1740	41.4	Shutdown
1770	41.5	
1800	41.5	
1830	41.5	
1860	41.6	
1890	41.6	
1920	41.6	
1950	41.7	
1980	41.7	
2010	41.7	