IPRO 319: New Technologies for Cardiac Arrest Victims

Final Report

Executive Summary

Over 250,000 people in the U.S. alone die annually from sudden cardiac arrest, and many of those that survive suffer brain damage, which can begin within minutes of the heart attack. Major risks among survivors include tissue damage, including brain damage. We are currently developing three life saving devices which could greatly decrease the risks which cardiac arrest victims face, and also save lives.

Purpose and Objectives

Our products work in conjunction with the use of an AED. Therefore, our products would be sold to the buyers of AEDs and any place that already has an AED. Currently, AEDs can be found in businesses, public facilities such as schools, health facilities, etc, and even in homes for private use by those most at risk for cardiac arrest. Certain states have even passed laws requiring the presence of AEDs in certain locations. The use of our technology and AED within the first three minutes could increase a victim's chance of survival by 70% and would significantly reduce brain damage. Since our devices work in conjunction with an AED, the AED market was analyzed as the target market. There are several different AED producers that supply AEDs to different people and organizations making it hard to know the exact number of AEDs sold per year. Cardiac Science, one of the leaders in the sale of AEDs, had $24.5 million in revenue worldwide. With the highest cost of their AEDs at $2495, they sold more than 9,800 units last year. This is only the number of new sales for one company. There are six major manufacturers of AEDS, and there are already thousands of purchased AEDs in other locations, making the potential market for our technology huge.

There are three projects within our IPRO that are also directed at minimizing cardiac arrest victim brain damage. A shaker is being developed which employs oscillation of the cardiac arrest victim along the spinal axis to increase blood flow, consequently reducing tissue damage. Currently under construction is a cooling vest that lowers the victim's body temperature. Research has shown cooling a victim's brain by 3°C can drastically reduce brain damage, and many major hospitals have long-term (12-24 hours) cooling units for cardiac arrest patients. The vest is designed to be on-site, similar to an AED and the shaker. Bystanders put the vest on the victim to initiate the cooling process, so that the brain is cooled sooner. The last project is a trans-dermal patch, which would slow the reuptake of oxygen upon resuscitation, also reducing tissue damage.

Organization and Approach

Within the first two weeks of the project, teams were established to allow members to focus on an area of interest. One team had the task of improving the shaker which was built last semester. Their tasks included modifying the previous shaker. They planned to design a new shaker with the addition of a motor. They also planned to modify the previous model to make it easier to use. Another team focused on designing the cooler vest. Their task was to modify the previous cooler model in order to make it more effective. They planned to develop a cooler which would maximize cooling by applying the device both underneath and on top of the cardiac arrest victim. The third team set to explore the aspects of a dermal patch to limit oxygen intake upon recovery. The final group focused on the business

aspects of the project. Their tasks included researching the scientific findings supporting our products, examining patents of similar products, determining market strategies for our products, researching aspects of animal and human testing and completing the IPRO deliverables. By organizing into teams we were able to spread the work load evenly among team members. This organization strategy also allowed us to improve the previous models while initiating a new technology to aid cardiac arrest victims. It also allowed research into the future of this IPRO and development of an eventual enPRO in which the marketing and production strategies would be the major focus.

Since there is a large amount of scientific papers supporting our products, literature review was the main research method employed in this project. Additional research was applied to determine the optimal materials to use for both models. Mathematical calculations were also performed to determine the optimal frequency for the shaker and also the required horsepower needed to provide whole body periodic acceleration by a motor. Another aspect of our research included communication with companies, which have products similar to ours, who provided research and suggestions for our project. As a team, we felt this approach was best suited to the needs of our project.

Analysis and Findings

Shaker

Chest compression has been the CPR method of choice for years, but a more effective method of CPR, known as Whole-Body Periodic Acceleration (WBPA), has been discovered, which involves oscillating the body back and forth along the spinal axis. Research shows this creates better blood flow than conventional chest compression CPR and drastically reduces brain damage. Our primary product is an on-site WBPA device. It uses a platform to support the victim and generates periodic acceleration via opposed torsion springs fastened to wheels. Bystanders place the victim properly on the board, and turn the device on, which automatically oscillates back and forth. The device would be implemented on a scale as to be mounted on walls near current AEDs in all major public and private areas. It is designed to be portable so that it can be taken to the victim.

If WBPA were initiated shortly after cardiac arrest, lives could be saved and brain damage could be hugely reduced. The problem is that although people have knowledge of this new technology, there is not yet a product that will serve this function on-site. There is an industry need for a way to implement this technology to minimize brain damage in all places where heart attacks may occur.

Improvements from last semester include the attachment of a motor on a new prototype. The new prototype also utilized a track system. This made the shaker easier to use. It also ensured that the oscillation was constant and maintained at the optimal frequency. The new prototype has better traction to the ground compared to the old one, there is less friction within the model due to low friction tracks, and has multiple linear springs that can be changed for different forces. The prototype sketch can be downloaded from igroups under the file folder called “shaker group”, it is a Google sketchup file which can be downloaded for free.

The original motor did not work on the new prototype. Although a different motor was purchased to replace it, it was not installed due to insufficient time. The new motor can also fit to the crankshaft used for the old motor; however, the new motor was from a circular saw and runs at 120v 60Hz, drawing 13amp, and achieving 2.5hp max and 5000rpm, therefore it will require a system to reduce the frequency to the desired frequency. The motor from the circular saw was much more powerful than required, but it is cheap and readily available. The system can be a 55:1 gear reduction or

power control circuit. In addition, work is needed to convert the motor‘s power source from AC power to DC for portability.

It was found that the force on the board during oscillation should be no greater than 300 Newtons, provided the oscillation would not be greater than 1.5 Hz or 90 rpm on the motor. Also the largest weight tested was 220 lbs. Data was acquired by connecting a load cell to the board, hooking the load cell up to a computer and moving the person, by hand, back and forth. Frequency was variable, weight was set per test, and the force was sampled 25 times per second. The test data can be found from the shaker test April 8.xlsx from shaker group section on igroups.

In addition, wheels can be added to the shaker so the board can be easily moved and brought to the victim. Weight is also an issue with the board, however it can be easily solved using different materials after the motor is successfully mounted and the prototype is working.

Cooler Vest

Therapeutic hypothermia is a medical treatment responsible for lowering a patient's body temperature to between 32–34 °C (90–93 °F), to help reduce the risk of the ischemic injury to tissue. Ischemic injury is a restriction in blood supply resulting in tissue damage. Insufficient blood flow may be a result of cardiac arrest or the occlusion of an artery due to strokes. Therapeutic hypothermia may be induced by invasive means, in which a catheter is placed in the inferior vena cava via the femoral vein, or by non-invasive means, usually involving chilled water blankets in direct contact with the patient's skin. Studies have demonstrated that patients at risk for ischemic brain injuries have better outcomes if treated with therapeutic hypothermia.

The earliest studies for the effects of hypothermia focused on slowing cellular metabolism caused by a drop in body temperature. For every one degree Celsius decrease in body temperature, cellular metabolism slows by 5-7%. Recent data suggests that even a small reduction in temperature can function as a neo-protectant. This is so because cells need oxygen to create ATP to regulate intracellular ion levels. Without oxygen, cells cannot manufacture the necessary ATP to regulate ion levels and thus cannot prevent the intracellular environment from approaching the ion concentration of the outside environment. Thus, a drop in body temperature helps prevent an influx of unwanted ions during an ischemic insult, by making the cell membrane more impermeable. Even a moderate decrease in temperature strengthens the cellular membrane, helping to minimize any disruption to the cellular environment. It is by moderating the disruption of homeostasis caused by a blockage of blood flow that results in hypothermia’s ability to minimize the trauma resultant from ischemic injuries.

Therapeutic hypothermia may also help to reduce reperfusion injury, caused by oxidative stress when the blood supply is restored to a tissue after a period of ischemia. Various inflammatory immune responses occur during reperfusion. These inflammatory responses cause increased intracranial pressure, which leads to cell injury and in some situations, cell death. Hypothermia has been shown to help moderate intracranial pressure and therefore to minimize the harmful effects of a patient’s inflammatory immune responses during reperfusion. The oxidation that occurs during reperfusion also increases free radical production. Since hypothermia reduces both intracranial pressure and free radical production, this might be yet another mechanism of action for hypothermia's therapeutic effect.

In 2002 the results of 2 randomized trials in Europe and Australia were published that compared mild hypothermia with normothermia (normal body temperature) in comatose survivors of out-of-hospital cardiac arrest. In the European study, patients that were randomly assigned to the hypothermia group underwent cooling to a target temperature of 32°C to 34°C by use of a cooling mattress and ice packs. The aim was to reach the target temperature within 4 hours of return of spontaneous circulation, maintain it for 24 hours, and follow with passive rewarming. In the Australian study, patients were

cooled by application of cold packs to the head and torso, to begin in the field before admission to the hospital. The target temperature of the hypothermia group was 33°C versus 37°C in the control group. Hypothermia was maintained for 12 hours after admission to the hospital, followed by active re-warming.

In the European study, 75 of the 137 patients (55%) in the hypothermia group for whom data were available had a favorable neurological outcome (able to live independently and work part-time) at 6 months compared with 54 of 137 (39%) in the normothermia group. At 6 months there were 56 deaths in the 137 participants (41%) in the hypothermia group versus 76 of 138 (55%) in the normothermia group. In the Australian study, 21 of 43 patients (49%) treated with hypothermia had good neurological function at discharge (to home or a rehabilitation facility) compared with 9 of 34 (26%) in the normothermia group. Mortality at discharge was 22 of 43 (51%) in the hypothermia group and 23 of 34 (68%) in the normothermia group.

Due to the two studies above, and many more, IPRO 319 has taken an initiative to create a more convenient method to begin the cooling process as soon as an individual goes into cardiac arrest. It is believed that our method will head start the individual in the cooling process, and also be a beneficial treatment because cooling will begin shortly after cardiac arrest.

Trans-dermal Patch

H_2S is a chemical used in a number of processes in the body, such as controlling blood pressure, regulating metabolism, and it is also known to ameliorate the side effects of anti-inflammatory drugs. The current research of H_2S indicates high doses of this particular gas may extend the lives of cardiac arrest victims by inducing a hibernate state. The objective of this hibernate state is to reduce the amount of damage caused by the flash of oxygen into the system after a successful resuscitation. It is believed that in a hibernate state an organism can reduce its oxygen needs and reduce its metabolic rate while simultaneously ceasing movement, breathing, and heartbeats. The life of the organism is suspended allowing cells to reduce their overall need for oxygen and sustain life. Dr. Mark Roth and the company he founded, Ikaria Inc., is currently in phase II human trials to test the hypothesis that hydrogen sulfide will improve the outcome in critical care medicine. Dr. Roth was funded by the U.S. Government for research on the H_2S chemical in order to produce a possible injection kit for soldiers on the battlefield. The idea is for those with life threatening injuries to be placed into a hibernate state so that, time allowing, life saving medical attention can be successfully implemented.

Because research is already being done on the production of H_2S injections we have decided to investigate another possible method of introducing the chemical into the blood stream. Trans-dermal patches are a means of chemical introduction for a variety of medicinal treatments. There are also many different types of patches that can be used depending on which type of drug is placed in the matrix of the patch. The company, 3M, was very generous in sending samples of supplies and also information regarding our project. We have also found several other companies willing to help universities with projects such as ours. Our contact at 3M, Ryan Gordon, PhD is very knowledgeable on the possible practical application of patches, and what is required to create one. He has also supplied us with the contact information of two other companies, one of which has supplied us with similar sample materials, which will also be useful resources when the time comes to create a prototype.

The creation of a patch with H_2S would provide a very important upgrade over the injectable version. It will increase the ease of use in public situations. This will allow the hibernate state to keep the victim safe during resuscitation with an AED device. The intention is to prevent the sudden rush of oxygen that flows into the body upon resuscitation to damage certain organs. During this period, the

most internal damage is done, inducing shock to many of the organs including the brain. So far as we know there is no work being performed which would create a patch that works in this manner. The thought of a topical cream was brought to our attention but then the dosage could not be controlled as easily as with a patch. One complication with the patch would be to create a level of absorbency which will provide a near instantaneous dose of H_2S so that medical relief may arrive shortly thereafter leaving as little internal damage as possible. Use of an ultrasonic device to increase the rate of absorbency was investigated as well. 3M produces a patch which contains polymeric micro needles that break through the skin barrier, which limits the size and type of molecules that may pass through. This type of patch allows the transmission of many drugs and may be useful for our currently unknown H_2S-containing solution. This type of patch is called Microstructure Trans-dermal Systems (3M, 2010).

Conclusions and Recommendations

Many accomplishments were achieved this semester. The shaker improved the prototype from last year by making it more efficient and user friendly. They also developed a new design and built a second prototype that included a motor. Both designs are closer to reaching the necessary frequency for oscillation to make the technology most effective and safe lives.

The cooling subgroup designed and created a prototype for a vest that includes a neck strap for cooling. This design takes advantage of the areas of the body most affected by cooling agents in order to reach the desired temperate to help lower brain damage in cardiac arrest victims. This technology will be attached to the shaker by Velcro. Consequently, when the emergency team arrives the vest can be worn during transportation to the hospital.

The patch subgroup conducted extensive research into the possibly patentable technology. However, the technology is being explored for other purposes and is still in the beginning stages of development.

The business subgroup compiled research and began to look into the research necessary to create a formal business report. Research was also conducted to determine an appropriate market as well as marketing strategies. Patents of similar products were also investigated. Applications to multiple competitions were also completed, highlighting the shaker technology.

In the future, testing will be a major aspect of this IPRO. This will provide definitive numbers and evidence that the prototypes are both effective and safe. Animal testing will be required first. Afterwards, human testing will be needed prior to FDA approval. A formal business plan must also be created which will outline the market need for this product in more detail. It must also identify different distribution channels. As mentioned before AEDs are sold through various online sites and distributors. Future groups should look into possibly selling the technologies through similar avenues. The business plan must also examine the large scale manufacturing costs of the technology including: raw materials, fixed costs, and labor.

Appendix

Table 1: Budget for shaker development

Item	Price/Unit	Quantity	Total Cost	Need for Item	Store Name
Electric Motor	$250	1	$250	Will be used to provide power to system.	www.omnimodels.com
Battery	$100	1	$100	Will provide energy to the motor.	www.mcmastercarr.com
Crack Arm	$100	1	$100	Will provide energy should the battery die.	www.mcmastercarr.com
Wood	$60		$60	1in. 24”x48” used as a foundation for the board	www.ebay.com
Carbon Fiber	$80		$80	Used as support for the wooden board.	www.mcmastercarr.com
Wheels	$20	2	$40	Used to allow the moving of the board.	www.mcmastercarr.com
Tracks	$10	2	$20	Dresser like tracks that will be attached to a plate used to create frictionless motion.	www.mcmastercarr.com
Springs	$4	4	$16	Used on wheels to insure the correct frequency of motion, and to make the energy used more efficient.	www.sears.com
Rubber Pad	$30		$30	Used to create traction between the track plate and the ground.	www.mcmaster.com

Total Cost for Shaker Development: $696.00

Table 2: Budget for cooler development

Item	Price/ Unit	Quantity	Total Cost	Need for Item	Store Name
Thermally Conductive Material (36” Silicone Rubber)	$200.00	1	$200.00	Used to retain cool temperature	http://www.stockwell.com
Insulating Material (Rubber)	$20.00	1	$20.00	Decrease Temperature loss	www.rubbersheetroll.com
Dust-Off compressed gas duster	$20.00	5	$100.00	Cooling supply	www.target.com

Total Cost of Cooler Development: $320.00

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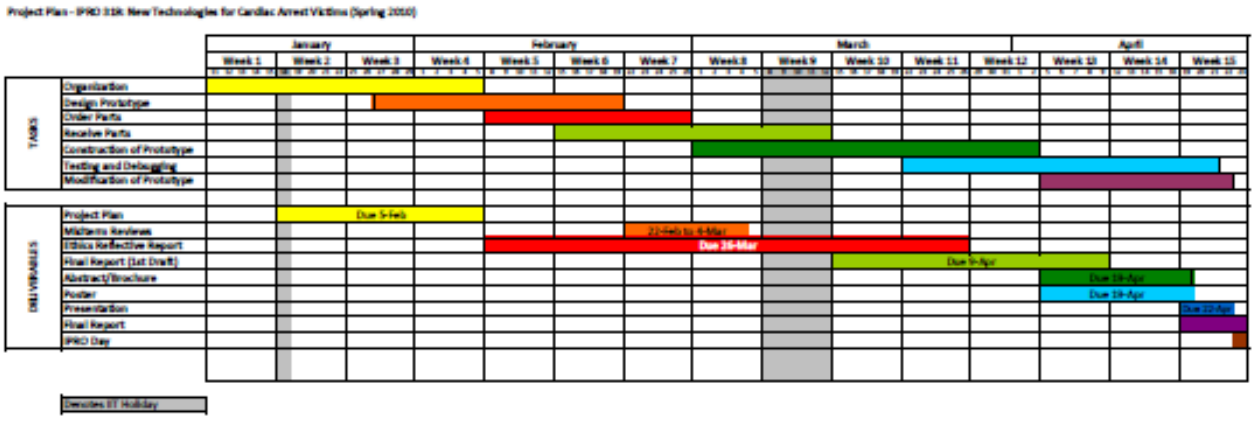

Figure 1: Project Plan

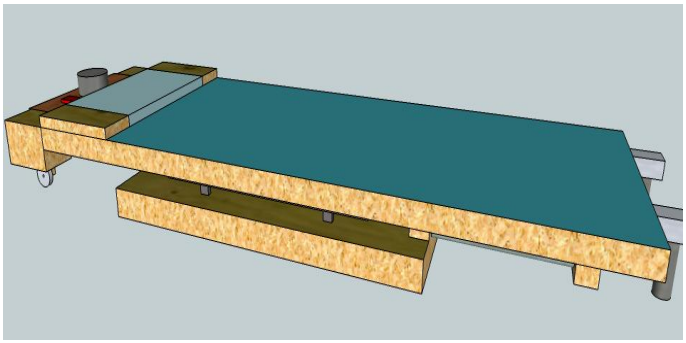

Figure 2: Shaker prototype

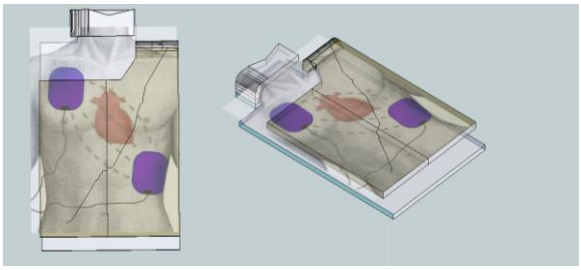

Figure 3: Cooler vest prototype