



March 15, 2016

Below are updates on some of the work performed with contributions from Faith's Angels and some of the upcoming next steps for these projects.

Histotripsy (Therapeutic Ultrasound) for the non-invasive treatment of congenital heart disease

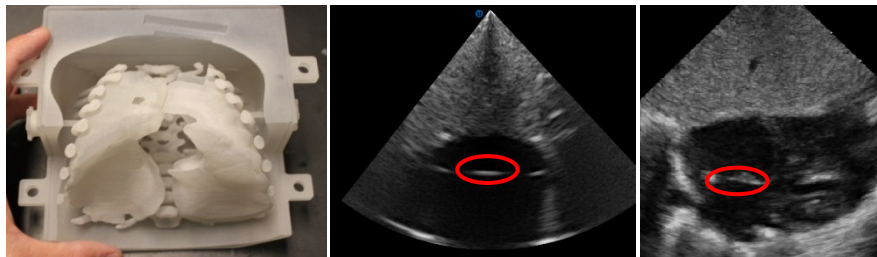


Image to the left represents a 3D printed replica of an infant torso generated from anatomic data. The middle image is the ultrasound image through this manikin once filled with tissue mimicking media. The image to the right is an ultrasound image of a human neonatal atrial septum which shows how similar the artificial replica mimics the human condition.

G012550 - Gabe Owens - \$15,000 - Gabe Owens Faith's Angels Congenital Heart Disease Award

Over the past year, with support from Faith's Angels and other generous contributors, our research team has continued to further the

development of the first ever therapeutic ultrasound device for the treatment of infants with congenital heart disease. Based feedback from the FDA in January 2015, the team has initiated and completed a clinical imaging study to optimize the design of the therapeutic transducer for life saving therapy of infants with HLHS. The transducers have been redesigned and optimized and have recently been delivered to our team from the manufacturer. The FDA has supported and pre-approved our plans for further pre-clinical animal testing prior to our official submission for approval for a clinical trial which we anticipate occurring in the next 6 months. In addition, we have designed and manufactured true-to-life replicas of infant torsos that we have been able to utilize for safety and efficacy testing, minimizing the necessity of animal experimentation.

Over the past year we have also applied for a Humanitarian Usage Device designation which we received in the fall of 2015. This designation will allow us to perform our clinical trial in infants with an emphasis on safety and once the trial concludes the device could then be used via a Humanitarian Device Exemption (HDE) mechanism, allowing easier access of the technology for patients throughout the country.

In addition to moving full forward with the neonatal HLHS application we have also began investigating other congenital heart lesions as well as other cardiovascular issues that infant with congenital heart disease suffer from. Specifically, many of our congenital heart disease patients suffer from blood clot or occluded vessels because of the therapy they require. We have been developing histotripsy to treat clotted vessels and restore blood flow. We have tested this in acute animal models and plan to move

Faith's Angels Inc. is a 501c3 nonprofit organization.

Faith's Angels
2633 11 Mile Road NW
Sparta, MI 49345

www.facebook.com/faithsangels
monica@faithsangels.org
616-887-5844



forward with long-term studies in the near future. In addition, venous catheter malfunction because of clot formation is also an issue for many of our patients. We have plans to utilize histotripsy technology to treat clogged catheters and potentially spare children in the future from repeated venous catheters and catheter associated infections. With the financial support of Faith's Angels we plan to initiate bench top studies and then move into animal studies to test our hypotheses. Between that endeavor and developing other application of histotripsy technology, such as fetal heart therapy, our team will be busy and is truly appreciative of the support from Faith's Angels. As the budgets increase (we anticipate utilizing most of the Faith's Angel budget within the next 8-12 months) we anticipate the data generated by these early studies will enable the obtainment of further funding through the NIH or American Heart Association. Gabe Owens, MD

G016416 - David Bradley - \$7,500 - Faith's Angels PM Project

"We devised a group of tests of our pacemaker power source on living animals and on cardiac preparations under simultaneous use by other research groups (ECMO Laboratory and Dr. Bocks animal experiments). This approach turns out to be much more economical than purchasing and housing animals of our own. It is also more of a respectful use of experimental animals to combine forces with another group. But it does require coordination. The proposed tests will be detailed assessments of the energy that can be harvested at the surface of the mammal heart, and also the effect of an energy harvester model on that heart surface. The concept of negative coupling—the idea that the energy harvester decreases the available vibrational energy simply by being there—needs to be investigated in developing this energy source for pacemakers. We now have the schedule of available animals and organ preparations, and will be fixing dates for the tests in the next 3 months." David Bradley, MD February 25, 2016

***G014639 - Ming Si - \$15,000 –
Faith's Angels Tissue Engineering Children's Research***

"Since the last update in 3-2015, we have made significant progress in the characterization and development of a novel stem cell isolated from discarded thymus tissue from neonates undergoing heart surgery, including the Norwood procedure. We have determined that these novel stem cells are especially potent in forming blood vessels and possess characteristics that would protect the heart (especially the single ventricle heart) from failing. We have demonstrated the therapeutic effects of this novel stem cell in an animal model of heart failure. We have also leveraged the blood vessel forming ability of these novel stem cells to engineered a blood vessel network in vitro. The blood vessel network we have created is by far more complex and comprehensive

Faith's Angels Inc. is a 501c3 nonprofit organization.

Faith's Angels
2633 11 Mile Road NW
Sparta, MI 49345

www.facebook.com/faithsangels
monica@faithsangels.org
616-887-5844



than other published descriptions in the scientific literature. In conclusion, interim results of our research have placed us in good position to continue our development of this novel stem cell type as a therapeutic agent for pediatric and HLHS related heart failure as well as continue the advancement of an engineered heart tissue patch with a vascular network that would provide immediate heart function, such as in a transplanted heart.”
Ming Si, MD February 25, 2016

Faith's Angels Inc. is a 501c3 nonprofit organization.

Faith's Angels
2633 11 Mile Road NW
Sparta, MI 49345

www.facebook.com/faithsangels
monica@faithsangels.org
616-887-5844