Each year in the United States, congestive heart failure affects more than 5 million people, and more than 500,000 new cases are diagnosed. On top of that, about 300,000 patients per year decompensate, or experience a loss of function in their hearts, to the point of needing a heart transplant. Unfortunately, only about 3,000 hearts are typically available on the national transplant list. Only the sickest, most desperate patients make the cut. Biomedical Engineer researcher John Criscione says he thinks he can help the rest.

"Everyone has their own heart," Criscione says. "We want to get theirs to work right."
“The heart never stops moving, so if the mechanics are different than what happens in a healthy heart, then that change in motion can kill the muscle. So motion is the most important factor in keeping heart muscle alive.”

**Correcting motion**

The endeavor started with the idea that motion was a key factor in heart growth.

“The heart never stops moving,” Criscione says. “So if the mechanics are different than what happens in a healthy heart, then that change in motion can kill the muscle. So motion is the most important factor in keeping heart muscle alive.”

Criscione is an expert in cardiac mechanics, the study of force and motion in the heart. In all muscle, he says, the type of force is tension, but motion differs in different types of muscle. In skeletal muscle, motion can consist of isometric contraction or elongation. In heart muscle, though, contraction is the only option: Other types of motion lead to cardiac muscle death.

“The heart always does positive work,” Criscione says, “taking blood and ejecting it against pressure. That contraction is the key motion for the heart.”

Heart disease, he says, is characterized by bad motion. With the rise of AED (automated external defibrillator) devices, aspirin therapy and education, more people are surviving heart attacks than ever. But the blockage in the coronary artery that caused the heart attack actually changes the motion of the heart, so surviving a heart attack is the number-one factor in end-stage heart failure.

“Imagine,” Criscione says, “if you lost the use of your quadriceps, what would your gait look like?”

Arrhythmias, or irregular heartbeats, can also lead to blockages and movement changes. Drugs can help restore proper motion because they lower the amount of work the heart needs to do. But, Criscione says, this approach doesn’t correct bad motion and only delays heart failure.

**Restoring proper motion**

Criscione says he wonders whether that bad motion in the heart is not a symptom of disease but rather a source.

“To test that, you’d have to be able to change the motion of the heart,” Criscione says. “Therapy could be beneficial to patients, but we need devices to help correct that bad motion.”

Criscione says that rehabilitating the heart after a heart attack might be possible—a kind of cardiac physical therapy.

“When something goes wrong with joints and muscles, we need mechanics to get back into shape,” Criscione says. “After a car accident or surgery, physical therapy can help repair the joint to become more functional. I think we can do the same for the heart.”

Criscione says such cardiac physical therapy would change the load on the heart, thereby changing the heart’s abnormal mechanics to guide good heart growth and operation.

To that end, Criscione has developed a device that fits around the heart. Pumping air into the chamber around the heart squeezes the heart and pushes blood out. Releasing the air allows the heart to expand and fill with blood.

Implanted after all other therapies have failed and patients are incapacitated from end-stage heart failure, the device could restore proper motion to the heart. Criscione’s invention modulates the growth of the heart but doesn’t replace the heart or its action. And unlike current devices on the market, Criscione’s heart-assist device does not come in contact with blood, which means less risk of infection or stroke.

**Dr. John C. Criscione**

Biomedical Engineering

979.845.5428

jccriscione@tamu.edu

As far as getting investors in CorInnova, Criscione says potential investors look at the commitment and experience of the people behind the idea first, and the idea itself second: The best idea with the wrong people won’t succeed because making mistakes is too easy in a highly complex and regulated marketplace such as health care. But, he says, even a mediocre idea can succeed if the people driving it are motivated and have succeeded in prior endeavors. Such individuals already know the potential pitfalls and have successful approaches to shepherd technologies through preclinical testing and premarket approval by the U.S. Food and Drug Administration.

In fact, the process thus far has been quite an education in commercialization, Criscione says.

**This experience has translated to the classroom, where Criscione teaches his students about regulatory affairs, design and development, preclinical testing, and clinical trials—things students will need to know to succeed in the biomedical device industry.**
MECHANICS

Restoring proper motion to save heart muscle

Each year in the United States, congestive heart failure affects more than 5 million people, and more than 500,000 new cases are diagnosed. On top of that, about 300,000 patients per year decompensate, or experience a loss of function in their hearts, to the point of needing a heart transplant. Unfortunately, only about 3,000 hearts are typically available on the national transplant list. Only the sickest, most desperate patients make the cut. Biomedical Engineer researcher John Criscione says he thinks he can help the rest.

"Everyone has their own heart," Criscione says. "We want to get theirs to work right."

"The risk in medical devices is the clinical trial and getting FDA approval because these are expensive, uncertain barriers to market that have to be completed before any revenue can be generated," he says. "If it succeeds in clinical trials, then the market will likely adopt it.

"In other technology areas like consumer electronics, there is no such barrier to market release for new products. The risk there is primarily related to market adoption."

This experience has translated to the classroom, where Criscione teaches his students about regulatory affairs, design and development, preclinical testing, and clinical trials—things students will need to know to succeed in the biomedical device industry.

Meanwhile, the work continues. The next step is design manufacturing and preclinical testing, and to complete this preclinical work and begin clinical trials—which can last up to two years themselves—could take three years. All told, it may be another five years until the device is ready for market.

That may sound like an eternity, but that’s typical for biomedical devices, Criscione says, which usually take 10 to 15 years to come to market.

"We’ve done a lot as a medical community to save people, which is good," Criscione says. "But now more people are surviving with damaged heart muscle, and I think we can restore proper motion so people will live even longer."

241 Zachry Engineering Center
3577 TAMU | College Station, TX 77843-3577
979.845.1322
TEES.TAMU.EDU

Scan the QR code with your smart device to view this story online, or visit engineeringmagazine.tamu.edu for more information.