San Antonio Express-News

NEWS//LOCAL

New invention by San Antonio scientist could be a 'game changer' in lifesaving heart transplants

Laura Garcia, Staff writer

March 15, 2021Updated: March 15, 2021 6:18 a.m.

The gold standard for transporting human organs has been the same for decades: an Igloo cooler.

Once a recipient has been identified, the organ is surgically removed from the donor's body in an operating room and placed in a Ziploc bag with preservation solution. It's put in two more plastic bags and placed on a bed of ice in a mini ice chest, much like you'd ice down a six-pack for a short trip.

"And then you run like the devil," said Leon Bunegin, a retired anesthesiology university professor in San Antonio.

The clock is ticking as medical staff rushes the cooler to the transplant site, trying to get there before the procured organ deteriorates to a point where it is rendered useless.

"The time limit is essentially four hours," Bunegin said. "After four hours, the major functions of the heart start to decline rapidly … after six hours the organ becomes non-transplantable."

And that would be a terrible waste considering that 17 people die every day in the U.S. waiting for an organ transplant.

Bunegin has worked on this problem for the past 40 years in his academic lab and may have found the solution. He's invented a new medical device called VP.S Encore that can keep a heart viable a lot longer than the ice chest method by pumping the organ with oxygen.

As chief scientific officer for Vascular Perfusion Solutions, a biotech company based in a tiny private lab in the South Texas Medical Center, Bunegin leads a team of scientists, engineers and medical experts, including some of his former students.

The team is testing his device, which is about the same size as the six-pack cooler but uses considerably advanced technology.

The company has begun the process of getting clearance from the U.S. Food and Drug Administration to use Bunegin's invention for human heart preservation and transport.

Preliminary findings show a pig heart can be kept viable as long as a day using the patent-pending perfusion technology that he designed.

"From an experimental standpoint, we've been able to keep the heart alive for 24 hours," Bunegin said.

A human heart could be kept viable for at least eight hours, twice as long as the current system.

Other organs could potentially be kept longer using his device, perhaps even several days.

The self-contained, single-use device uses oxygen to preserve vascularized tissue and is in a carry-on case designed to fit inside the overhead compartment of a commercial airliner.

On ExpressNews.com: San Antonio's University Hospital part of study to improve transplants

Led by CEO Tom DeBrooke and President Mark Muller, VPS has already raised about $5 million in equity funding from unnamed investors, according to federal Securities and Exchange Commission filings.

The company also has secured big names for its scientific advisory council, including pediatric transplant surgeon Dr. Francisco G. Cigarroa, past president of UT Health San Antonio; and retired U.S. Air Force Maj. Gen. Byron C. Hepburn, who previously ran the San Antonio Military Health System.

Back in 2009, Bunegin started a company with DeBrooke called Paragonix Technologies. His technology is behind the medical device maker's cardiac transport system SherpaPak, which is already on the market. They continue to own a portion of Paragonix.

Bunegin also invented the ULiSSES, an early version of his current perfusion device, and VPS has an exclusive license to market the technology.

The company was awarded a $1 million U.S. Department of Defense grant to study whether the device could keep limbs severed on the battlefield viable until they can be surgically reattached at a hospital.

VPS has also filed a series of patents on its own VP.S Encore technology, which is more efficient and easier to manufacture than ULiSSES.

'A long day'

On this Sunday morning, a still viable pig heart arrived in the standard blue and white Playmate cooler.

Rafael Veraza, director of translational research at VPS, carried the organ inside the lab and started to prepare it for what would be a very long day of scientific observation, testing and analysis.

Veraza trimmed away some extra tissue left behind during surgery that had taken place about two hours earlier.

To prove the device works, the team needs to mimic the real-life human procurement process as best as possible, so the company works with area veterinary surgeons to get pig hearts, which are close enough to a human heart in anatomy and function that they are often used for medical training.

VPS must gather more research data before the device can undergo pre-clinical testing in a government-regulated lab, still using pig hearts. Later, if all goes well, the FDA will clear the device for clinical testing using donated human hearts.

On this day, everyone in the scene was focused on keeping the non-beating pig heart alive. It's not every day the team has the opportunity to work on a live heart.

Engineering Director Isreal Jessop carefully installed a thin tube called a cannula into one of the heart's valves, which allows the device to deliver a cold oxygenated solution that keeps tissue from degrading.

Jessop's brows stayed furrowed as he handled troubleshooting the delicate process.

The plump pink heart floated in a solution in a clear jar, kept in a hyperthermic state for the next eight hours. Tiny sensors placed inside sent real-time data to a nearby laptop.

Clinical Director Michelle Watt, a registered nurse, made sure times and measurements were documented on a big white board in the room and kept everyone on schedule.

DeBrooke marveled at the heart while trying to stay out of the way. He leaned in to snap a few photos on his cellphone.

Senior Scientist Kristina Andrijauskaite took tiny samples from the heart and put them in a machine typically used in hospitals to measure glucose, sodium and calcium levels.

She keyed in “007” to identify the heart for lab records. Later, the team dubbed the heart “James.”

The team’s previous subject, Chester, was sitting in a glass jar on a nearby counter.

Andrijauskaite said she would freeze most of the samples taken with plans to study them during the week looking for genetic markers that indicate damage.

“Our eventual goal is to silence those genes so that there’s less of a chance of rejection (after transplant),” she said.

Before this job, she studied cancer and the body’s response to chronic stress. She was also part of a team at UT Health San Antonio that sent live zebrafish embryos via rocket to space.

Later in the evening, Research Engineer Riley Lopez helped conduct an experiment using an instrument called a Langendorff — a glass contraption with multiple tubes located in another part of the lab.

“There’s only a few labs in the country that have a system this big for pigs,” Veraza said.

After eight hours, the team took the heart out of Bunegin’s device and simulated what would happen during a transplant by bringing the heart’s temperature from around 4 degrees to 37 degrees.

They continued working with the pig heart until nearly midnight.

FDA approval

It’s a long road to FDA approval, but the process is designed to ensure that medical devices marketed to the public are safe.

On Feb. 8, the FDA designated the VP.S Encore as a breakthrough device. This federal program allows manufacturers to communicate with FDA experts during

the pre-market review phase of devices intended to treat or diagnose life-threatening or debilitating disease or conditions.

U.S. government officials report that more than 107,000 people are currently on the national transplant waiting list as of February with the vast majority in need of a kidney, but others needing a liver, heart or lungs.

Within the past six months, nearly 1 in 5 available hearts were declined primarily because a donor and recipient were too far away from each other, said Clarissa Thompson, a spokeswoman with San Antonio-based nonprofit Texas Organ Sharing Alliance.

The alliance is one of 57 federally-designated organ procurement organizations in the U.S. responsible for recovering organs from deceased donors for transplantation.

Under a new partnership, the alliance will provide human hearts to VPS once it's ready for that level of testing. Thompson said these are hearts donated for research that aren't viable for transplantation.

If a device like the one VPS created makes it to market, it'll be a gamechanger for the organ donation industry.

Organs would not only be able to get to patients in need who live farther away, Thompson said, but they could arrive in better condition, leading to fewer rejections.

"This could mean more lives saved and possibly a shorter wait time (for those on the list)," she said.

laura.garcia@express-news.net

Article with photos: https://www.expressnews.com/news/local/article/New-invention-by-San-Antonio-scientist-could-be-a-16026123.php#photo-20743184