Artificial Lung Helps Patients Breathe Easier

University of Pittsburgh

A 76-year-old woman with chronic emphysema was admitted to a hospital in India earlier this year. She was complaining of shortness of breath and was diagnosed as being in respiratory failure, meaning she had a buildup of carbon dioxide in her lungs and couldn't take deep enough breaths to push it out and suck in oxygen instead.

Normally doctors would put such a patient on a mechanical ventilator, which would mean sedating her so they could insert a breathing tube down her throat. Instead, her doctors decided she was the ideal person to be enrolled as the first patient in a study of a new artificial lung initially developed by researchers at the University of Pittsburgh, called the Hemolung.

The device is connected to a patient by a catheter. It pumps blood out of the patient, runs it across a bundle of fibers that pull out carbon dioxide and infuse oxygen, then sends the blood back into the patient, thus doing about 50 percent of the work of the person's failing lungs.

> *The woman was hooked up to the Hemolung and quickly began breathing more easily. By the*

> *time it was removed three days later, her carbon dioxide levels were down, and she could breathe on her own. Equally importantly, she had avoided needing to be put on a mechanical ventilator and, therefore, spent her time in the hospital alert and able to eat and talk with her family.*

"It was very rewarding to see that happen," says Nick Kuhn, chief operating officer (COO) of ALung Technologies, the Pittsburgh company developing the Hemolung. ALung is hoping to finish its first clinical trial on patients in Europe and

India early next year and then apply for approval in the United States. The goal is to be able to help the 450,000 people in this country and millions more worldwide avoid temporary hookup to a ventilator, thus granting them a shorter and more comfortable stay in the hospital.

Carbon Dioxide out and Oxygen in

The innovation grew out of work in the Medical Devices Laboratory at the University of Pittsburgh. The external device now known as the Hemolung has changed shape considerably, having started as an internal device. Professors Brack Hattler, M.D., Ph.D., and William Federspiel, Ph.D., designed what they called the Hattler catheter in the mid-1990s. The catheter held a series of tiny hollow fiber tubes that were bundled together and was inserted into a patient's large vein during respiratory failure. The tubes had oxygen running through them, so when the patient's blood ran across them, it picked up oxygen and left behind carbon dioxide.

ALung is focusing on two types of potential patients, those with chronic obstructive pulmonary disease (COPD) and those with acute respiratory distress syndrome (ARDS). COPD patients, who often have emphysema, have trouble breathing deeply because the airways in their lungs are restricted, having grown stiff or swollen over the years. ARDS patients' lungs have been damaged as a result of another disease or accident, and they tend to develop ARDS while in the hospital.

In its first trial, ALung is looking at the Hemolung's effect on people with COPD who have a sudden drop in respiratory function.

"They could get a cold or a flu or anything that puts these patients over the edge," Federspiel explains. "If you or I get a bad cold in the winter, we don't have to go to the intensive care unit because we breathe fine. If they get a bad cold, they can't breath."

The artificial lung is a temporary device needed to get them through that period of acute need, usually three to four days. "Eventually the cold or flu resolves itself and they get better," he says.

Starting a Company

Hattler, who died in 2008, and Federspiel patented the catheter-based artificial lung with the help of the University of Pittsburgh's Office of Technology Management (OTM) and founded ALung in 1997. They didn't have any plans to commercialize the device at the time, but needed to work with a company to apply for grants. The research has been funded by the National Institutes of Health, the U.S. Department of Defense and the U.S. Army.

By 2001, they were presenting their idea at scientific conferences and had started generating enthusiasm for an actual catheter-based device, Federspiel says. They couldn't find an established company interested in licensing the technology, so they decided to set out on their own.

But first they needed to negotiate a one year licensing option with the university, explains Maria Vanegas, OTM technology licensing associate. The office generally grants options to startups because this strategy is a simpler and less expensive way to investigate whether there really is a market for the product. Startups can use that year to perform due diligence on the technology and to start fundraising, she says.

They also brought in an outside chief executive officer for the first time, choosing Kuhn (who switched to COO in 2009), a veteran of other medical device companies. Kuhn worked at raising money, while Hattler and Federspiel toiled in the lab to make the catheter as small as possible. After the one-year option was up, the company fully licensed the technology.

In 2005, they found that the miniaturization of the catheter device topped out at about 1 centimeter in diameter. While it worked well in animal studies, the scientific advisory board assembled by Kuhn opined that such a large a catheter would be unappealing to many medical professionals.

“It became obvious that we needed to make a change,” Kuhn says.

After much deliberation, they decided to scrap the Hattler catheter and turned to a related innovation — the one that eventually became the Hemolung.

Breathing New Life Into the Project

Federspiel had been working on another iteration of the technology that used the same fiber bundle but positioned it outside the body. Because the bundle didn’t have to get inside the person’s vein, the catheter size dropped to 5 millimeters in diameter, the same size used in kidney dialysis.

There was a precedent for an external artificial lung. A technology called extracorporeal membrane oxygenation (ECMO) is used at a small number of hospitals in the country. It removes a patient’s blood, adjusts the gas levels and then pumps it back into the body. But, because it removes two to three liters of blood a minute, the patient has to be very carefully monitored.

“If there’s a complication in the line, they could bleed out,” Federspiel says. “The technology is considered very invasive and complex.”

Federspiel figured that if he could come up with a way to remove sufficient carbon dioxide using a much smaller amount of blood per minute, the technology would be a far more attractive. But removing less blood meant that the artificial lung had to be more efficient in restoring the correct carbon dioxide and oxygen levels to have the same desired effect.

That’s when he had the idea of rotating the fibers. Spinning the fibers allows them to come into contact with more blood as it’s pumped out and so it works more efficiently, Federspiel explains. The Hemolung removes about 400 milliliters of blood a minute, or between a 5th and a 10th as much as the ECMO machine. ALung changed the design while retaining the concept so that the blood now rotates around stationary fibers rather than the opposite.

ALung is now focusing exclusively on the Hemolung. While this switch has slowed down the company’s plans for generating a product, everyone agrees that it has made the device much more marketable. Vanegas applauds Hattler and Federspiel’s determination to see the project succeed, despite the initial setback.

“It’s unique when you find dedicated inventors who don’t get frustrated with the process, especially when they had one device and then had to switch,” she says.

For patients like the woman in India, the device's long evolution was definitely worth it, both for the medical care it provides and the ability to avoid being hooked to a ventilator.

"They're able to move around, get out of bed," Federspiel says. "They have the ability to eat normally, talk normally and express how they're feeling. It's a significant quality-of-life improvement."

This story was originally published in 2010.

To see available technologies from research institutions, click here to visit the AUTM Innovation Marketplace.