3-D printed windpipe gives infant breath of life

A flexible, absorbable tube helps a baby boy breathe, and heralds a future of body parts printed on command.

Marissa Fessenden

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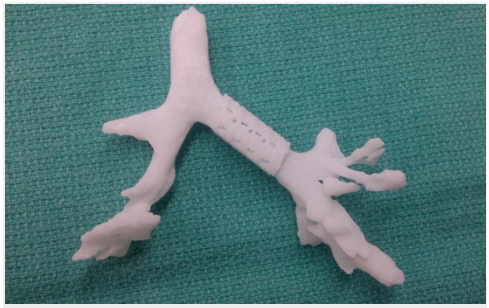

University of Michigan

Kaiba Gionfriddo was six weeks old when he suddenly stopped breathing and turned blue at a restaurant. Kaiba's parents quickly rushed him to the hospital where they learned that his left bronchial tube had collapsed because of a previously undetected birth defect. During the next few weeks the life-threatening attacks recurred, increasing in number until they became everyday events. Physicians and researchers, however, used some of the most sophisticated bioengineering techniques available to 3-D print a synthetic tube to hold the baby's airway open. Kaiba had the surgery in January 2012 and hasn't suffered an airway collapse since.

The trachea, or windpipe, is essentially constructed much like a vacuum cleaner hose, says Glenn Green, an ear nose and throat specialist (otolaryngologist) at the University of Michigan, who helped to develop the device. The human trachea comprises 20 rings of cartilage linked by muscle and connective tissue that extends from the Adam's apple down behind the breastbone. It then branches into two tubes called bronchi that each connect to a lung. With each inhalation, the lungs fill and expand; likewise, the strong but flexible airway tubes widen and lengthen.

In most cases after a child is born, the cartilage in the trachea keeps the airway open. But in about one out of 2,100 live births, for some reason, a portion of the airway is floppy and collapses, blocking outside air from reaching one or both lungs. Treatment for this kind of condition—called an airway malacias—includes close monitoring during colds and other respiratory infections, but some people may need a respirator to keep their airways open or surgery to insert a breathing tube until the danger has passed. Surgical treatments for persistent cases include using a structure inside the airway to prop it open—a stent—but that approach irritates the trachea, says John Bent, an associate professor at the Albert Einstein College of Medicine and director of pediatric otolaryngology at Montefiore Medical Center in New York City. Or doctors may take a piece of the patient's rib and use it around the outside of the trachea as a splint. "But that doesn't give [the airway] the right shape," he says, or the ability to expand and contract with each breath.

For unknown reasons, however, some cases are extremely severe. Those infants, including Kaiba, struggle to breathe even after treatment.

Fresh out of options, Kaiba's doctors contacted Green and his colleagues who were working on a new device that could help. The researchers had been searching for a way to help infants with collapsing airways. They designed a tube that could wrap around the floppy portion of a trachea or bronchus and hold the airway open. Each individual's airway, however, is unique, and there is no one-size-fits-all solution. Instead Green and his colleagues would create custom-designed devices using technology called three-dimensional printing.

A 3-D printer works like an inkjet printer, but instead of laying down layers of ink it deposits a structural material. The printer head adds each layer according to a digital pattern to create a 3-D structure. 3-D printers in manufacturing have built prototypes and parts for machines. In research settings bioengineers have created artificial ears, and lab rats have received printed spinal disks and bones. Printing fully functioning organs and tissues for humans poses some challenges. A kidney, for example, needs working blood vessels and tubes to collect urine.

Problems with the trachea, however, lend themselves to 3-D printed solutions because the organ's ridged tubelike structure is simple. After testing their idea in piglets, Green and his colleagues were confident a printed device would work. Scott Hollister, a professor of biomedical engineering at Michigan was in charge of designing sleeve that would wrap around the outside of the floppy airway. The sleeve's structure allows it to expand as the airway grows and develops while simultaneously resisting spasms that pull inward, thereby collapsing the airway.

The team first used a computed tomography (CT) scan to sketch out Kaiba's airways. From those images, they then sculpted a three-dimensional printed cast that had the same shape as Kaiba's collapsed bronchus. Using that cast they created the sleeve or splint that would wrap around the bronchus. It took several tries but the researchers were eventually able to create a perfect fit. The next step was to sew the tissue of Kaiba's bronchus to the inside of the sleeve. The team needed to obtain an emergency-use approval from the U.S. Food and Drug Administration before they could implant the device. "When we put the splint on, we saw his lungs move for the first time," Green says. As Kaiba grows, the device should expand with him.

The tube itself was printed in layers of a biocompatible plastic called polycaprolactone. The 3-D printer heats up a powdered form of the plastic until it melts and can be extruded in a paste. After a few years inside a body the tube will dissolve—it is made of the same material used for sutures—and by that time his bronchus should have grown strong enough to function normally.

Kaiba's tube is the first time a 3-D printed device has been implanted in a patient to aid tissue reconstruction. The research team reported the case on May 22 in *The New England Journal of Medicine*.

"It's a very nice approach to using technology to treat a problem that has not a lot of good solutions," says Robert Weatherly, an associate professor of otolaryngology at the University of Kansas School of Medicine and a physician at Children's Mercy Hospital in Kansas City, Mo., who was not involved in the study. He points out that the approach is different from a typical tissue engineering approach because Kaiba's bronchus tissue was present but not functioning; here the 3-D device reinforces underdeveloped tissue. In other cases tissue is absent and needs to be rebuilt from scratch—as in a recent case of a young girl with an absent trachea. Her doctors built a transplantable trachea of plastic incubated with the child's own stem cells. Unlike Kaiba, however, she will need a bigger windpipe when she grows.

The critical next steps to making the technology more available are clinical trials, along with tracking patients over a longer period of time to see how they fare with 3-D printed parts.

The use of 3-D printed devices and body parts is still in its infancy. Cartilage and bone will be the first solutions to reach wide use, Green says, adding there is a "gigantic potential," for the future.

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