Bionic Pancreas for Type 1 Diabetes

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by Dr. Francis Collins

From taking selfies to playing Candy Crush, smart phones are being put to a lot of entertaining uses. But today I’d like to share an exciting new use of mobile health (mHealth) technology that may help to save lives and reduce disability among people with type 1 diabetes—an advance inspired by one researcher’s desire to help his son.

By teaming a smart phone with a continuous glucose monitor and two pumps designed to deliver precise doses of hormones, a team from Boston has created a bionic pancreas that appears to control blood glucose levels in people with type 1 diabetes more effectively than current methods. That is a significant achievement because if blood glucose levels are either too high or too low, there can be serious health consequences.

In a healthy body, the pancreas masterfully regulates blood glucose levels by orchestrating the secretion of insulin and another hormone, called glucagon, which raises blood glucose. These hormones work together like an automatic thermostat, raising and lowering blood glucose when appropriate. However, in type 1 diabetes, the pancreas produces little or no insulin, leading to increased levels of glucose that gradually damage blood vessels, kidneys, and nerves, raising the risk of blindness and amputations.

To prevent such damage, people with type 1 diabetes must receive supplemental insulin. Yet if people with diabetes take too much insulin, don’t eat properly, or experience physical or mental stress, their blood glucose levels may drop too low—a condition called hypoglycemia that may cause seizures or even death.

As anyone with type 1 diabetes knows, it’s difficult and frustrating to regulate glucose levels precisely using man-made technologies. For most people with diabetes, this requires frequent finger pricks and measurement of glucose levels with a monitor. Based on those readings, a patient must calculate the correct dose of insulin and then inject the insulin with a syringe or “pen.” That’s a lot of finger pricks and needle sticks every day—and still the glucose regulation may not be as tight as desired. Continuous insulin infusion pumps can help to reduce the need for repeated syringe injections, but still require frequent finger pricks so patients or caregivers can calculate the correct dose.

Boston University bioengineer Edward Damiano had a very personal reason for wanting a system that
more closely emulates a normal pancreas: his son, David, who has type 1 diabetes. Like many other parents, Damiano worried that hypoglycemia would strike his child at a time when his blood glucose levels were not being monitored, for example, when he was asleep.

In fact, ever since David was diagnosed at the age of 11 months, Damiano would slip into the boy’s room several times a night to test his blood glucose; pricking his fingers or toes with a lance and analyzing the samples with a glucose meter. If David’s glucose level was too high, Damiano would give him a dose of insulin through a continuous infusion pump connected to the boy’s body via a tiny needle; if the glucose level was too low, he’d give the boy some juice and/or reduce his insulin dose.

What Damiano really wanted was a bionic pancreas that would keep watch over David 24/7 and deliver the correct hormones to balance his blood glucose levels. So, Damiano and his biomedical engineering colleague, Firas El-Khatib, set out to do just that, using off-the-shelf components.

The first component of their bionic pancreas system is a continuous glucose monitor capable of wirelessly transmitting its readings to a smart phone. The second component is an iPhone 4S, programed with an app that Damiano and El-Khatib developed to calculate the correct dose of insulin. As an extra safety step, the program was also designed to calculate the dose of glucagon to give if blood sugar levels fell too low. After making the calculations, the phone wirelessly transmits dosage commands to the third and fourth components: an insulin pump and a glucagon pump, which deliver the precise dose of the hormones via tiny needles inserted under the abdomen’s skin. Once in the bloodstream, the two hormones work in tandem to keep blood glucose from getting either too high or too low.

This bionic pancreas system, which fits neatly into a fanny pack or large pocket, measures patients’ blood glucose levels and adjusts their hormone doses every 5 minutes around the clock. That’s a total of 288 therapeutic decisions every 24 hours!

After developing this device, Damiano and El-Khatib worked with Steven Russell, a diabetes specialist at Massachusetts General Hospital in Boston, to test it in 20 adults and 32 adolescents with type 1 diabetes. During the five-day clinical trial, the adults lived in a hotel, but were free, under the supervision of a nurse, to eat, drink, and move about as they normally would at home. The adolescent trial was similar, but held at a summer camp for kids with diabetes.

In findings published in *The New England Journal of Medicine* [1], the bionic pancreas helped people with type 1 diabetes achieve more stable blood glucose levels than those achieved with a conventional insulin pump. What’s more, adults using the bionic pancreas experienced about 40% fewer hypoglycemic episodes and adolescents, 50% fewer.

As encouraging as these preliminary results may be, there’s still more work to be done before this device is ready for the market. Damiano and his colleagues have just launched a larger, multicenter clinical trial that will follow 40 adults for 11 days at home. Another trial with preadolescents, between 6 and 11 years old, will run this summer.

The Boston bioengineers are also heading back to their work bench with the goal of creating a smaller,
more streamlined version that can be tested in humans by 2016. And I’m betting they’ll make it because “Dad” Damiano has a deadline. David goes off to college in the fall of 2017. Maybe by then, there will be a convenient, reliable device that can enable David, his parents, and so many others whose lives are affected by type 1 diabetes to sleep peacefully through the night?

Reference:


Links:

Edward Damiano

Bionic Pancreas: Clinical Trials

Fast Facts on Diabetes, National Institute of Diabetes and Digestive and Kidney Diseases

NIH Support: National Institute of Diabetes and Digestive and Kidney Diseases