

Artificial pancreas has potential to change lives for diabetics

By Valerie Clark - published 3/12/12 @ Patexia.com



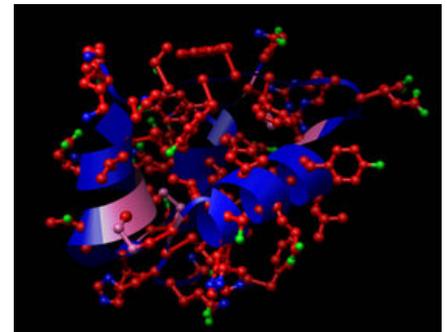
Competing medical device manufacturers are racing to get an artificial pancreas to the market. The FDA has yet to approve specific artificial pancreas technology for outpatient use, but they have released guidelines to move this research forward. Two stand-out companies are currently leading this race, and their innovations hold great promise for the diabetic community -- once new artificial pancreas technology reaches the US market for in-home use, it will change lives for type 1 diabetics.

An artificial pancreas is not exactly what you might imagine based on the name. It's not like an organ transplant or artificial limb. The technology is called an artificial pancreas because it makes up for the lack of a functioning pancreas for people with diabetes. It's a self-adjusting device that monitors glucose levels in blood or plasma and releases insulin when glucose levels decline. It does not produce insulin like a normally functioning pancreas, but it does improve the way diabetes is managed.

In non-diabetics, the pancreas is responsible for producing insulin and maintaining normal glucose levels in the blood. When the pancreas isn't working properly, the body cannot maintain glucose levels sufficiently. When glucose levels are too low, serious health risks can occur for diabetics.

For diabetics, an artificial pancreas means no more constant monitoring, no more manual insulin injections and reduced health risks. These benefits will ultimately improve the quality of life for diabetics because many sufferers must measure glucose levels every 3 hours, 24 hours a day.

The most promising designs for the artificial pancreas device include an implanted RFID microchip that senses glucose levels in plasma from PositiveID (PSID), and an external box worn by a patient with leads attached to the skin from Medtronic. The PSID innovation is called "Glucochip." The Medtronic device is part of a "MiniMed paradigm insulin deliver system," also known as the "ASPIRE (Automation to Simulate Pancreatic Insulin REsponse)" study. No matter which design gets to the market first, the ultimate result will be a revolutionary alternative to the standard glucose monitor and insulin pump. There is no clear indication yet of what the device will cost and whether or not health insurance will contribute.



In October 2011, Medtronic obtained FDA approval for an in-home investigational device exception (IDE) study. Reportedly, 19 percent of test subjects who wore the MiniMed device spent less time below the low-glucose threshold than subjects using a traditional pump during in-patient clinical studies. These results may propel Medtronic ahead of PSID in the race to get this technology to the market; however, I imagine there will be room for more than one device in the market given the variations between the two designs.

One of the biggest advantages with this new technology, and a high priority for device manufacturers, is the indication for nocturnal hyperglycemia. This is a scary and very real risk for people with type 1 diabetes. The worst case scenario is that someone becomes unconscious while sleeping because of dangerous, undetected glucose levels. The advantage of the Glucochip and MiniMed Paradigm is automatic release of insulin into the blood stream when glucose is too low.

A touching story about a 12-year old girl and her battle with diabetes was shared recently on CNN. This young girl had the opportunity to participate in a 3-day trial with an artificial pancreas in her home. She normally has to prick her finger 10-12 times a day and estimate how much insulin to inject into her body. During the 3-day period, she stayed at Massachusetts General Hospital and remained connected to a laptop for the trial, but she enjoyed the freedom from her daily routine none-the-less. She got a brief taste of how this technology could change her life.