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Emerging Technologies in Diabetes Research

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Novel Artificial Pancreas System Successfully Controls Blood Sugar in Adults With Type 1 Diabetes

A recent clinical trial has revealed the benefits of a unique artificial pancreas system – one that uses two hormones, instead of just one, to control blood sugar levels.

Using the system, all study participants were able to achieve near-normal blood sugar levels for more than 24 hours without experiencing hypoglycemia, or low blood sugar. Results from the study, which was co-funded by JDRF, were reported this spring in the journal *Science Translational Medicine*.

A two-hormone approach

In the study, researchers from Boston University and Massachusetts General Hospital tested the safety and efficacy of a novel closed-loop system that incorporated glucagon in addition to insulin. The researchers added glucagon to the system to more closely mimic the physiology of a person without diabetes.

Glucagon is a naturally occurring hormone that counters the actions of insulin, raising blood sugar in response to hypoglycemia. Like insulin, its production is impaired in people with type 1 diabetes. Unlike insulin, glucagon is not currently used as a routine part of type 1 diabetes therapy, though it is used in large doses to treat people during low blood sugar emergencies.

The artificial pancreas system in this trial combined the classic elements used in other studies: a sensor to monitor glucose levels and infusion pumps (here, one for each hormone) controlled by a sophisticated computer program called an algorithm. The algorithm determined the appropriate insulin and glucagon dosages to deliver, based on blood glucose levels relayed to it by the sensor.

The system was designed to counteract moderate drops in blood sugar by infusing minute doses of glucagon throughout the day, similar to what the body does in people without diabetes, according to Edward Damiano, Ph.D., associate professor of biomedical engineering at Boston University and the study's senior author.

In this issue:

Main findings

The trial enrolled 11 adults with type 1 diabetes, who wore the system for 27 hours. Participants ate three high-carbohydrate meals and slept overnight at the hospital. In the study's first phase, six participants achieved an average blood glucose level of 140 mg/dl without experiencing hypoglycemia – substantially below the American Diabetes Association's recommended target level of less than or equal to 154 mg/dl. The other participants exhibited some degree of hypoglycemia, which was traced to individual variation in insulin metabolism. In the trial's second phase, the researchers adjusted the system to reflect a slower insulin absorption rate. The result: none of the participants experienced significant hypoglycemia. Although the average blood sugar level for the entire group was slightly higher after the adjustment (164 mg/dl), this level remained near the recommended target.

"This study is proof-of-principle that the use of glucagon in artificial pancreas systems can be beneficial and important in lowering the risk of low blood sugar emergencies," said Aaron Kowalski, Ph.D., Director of the JDRF Artificial Pancreas Project. "It also provides us with important insight about the role that the rate of insulin absorption will play in customizing algorithms that will drive these systems so that they function optimally."

A milestone for JDRF's Artificial Pancreas Project

This study is the latest development within JDRF's Artificial Pancreas Project, and stems from progress that has been made since 2006 by the JDRF-funded Artificial Pancreas Consortium. The Consortium is a group of university-based mathematicians, engineers, and diabetes experts who have

developed the computer programs needed for an artificial pancreas, and established their scientific feasibility.

These academic studies complement JDRF's work with industry partners, who are driving the development of first-generation systems. JDRF announced the first major non-exclusive industry initiative of the Artificial Pancreas Project earlier this year, when it entered into a partnership with Animas, a Johnson & Johnson company, to develop a first-generation artificial pancreas system. JDRF also announced a non-exclusive partnership with BD (Becton, Dickinson and Company), aimed at developing novel insulin delivery products to enhance insulin pumps – a key component of safe and effective artificial pancreas systems. For more information on these and other developments, please visit www.artificialpancreasproject.com.

Underway: A Global Effort to Develop the Artificial Pancreas

This spring, a consortium of European academic and industry partners announced a collaboration called AP@home. Much like JDRF's Artificial Pancreas Project, AP@home aims to develop an artificial pancreas that would allow automated blood sugar control for people with type 1 diabetes.

An advanced artificial pancreas system – a device that uses continuous glucose monitor (CGM) data to automatically administer appropriate doses of insulin through a pump – could not only improve the quality of life for people with diabetes but also help to control their blood sugar levels, lowering their risk for complications.

"AP@home offers a tremendous opportunity to advance the development of artificial pancreas systems," said Aaron Kowalski, Ph.D., Director of JDRF's Artificial Pancreas Project. "The collaboration between researchers in the European consortium and in JDRF's Artificial Pancreas Project will create a global partnership that can dramatically improve the lives of people around the world living with diabetes."

A closer look

Like JDRF's Artificial Pancreas Project, the AP@home consortium will bring together world-leading experts in the fields of medical device development, clinical studies, and the modeling of control algorithms – the computer programs that link insulin pumps with CGMs and calculate the dose of insulin to deliver. Thus far, AP@home includes seven academic partners and five industrial partners (Profil Institut für Stoffwechselforschung GmbH; Triteq Ltd; Sensile Medical AG; STMicroelectronics; and 4a engineering GmbH). The project is funded by a €10.5M grant from the European Commission.

In the first phase of AP@home, researchers will test currently available artificial pancreas algorithms with CGM systems and insulin pumps already on the market. This system will involve a "two-port" approach that requires two skin punctures to attach the glucose monitor and the insulin pump. In this stage, the aim will be to improve both the accuracy of the glucose sensors (a component of the CGM) and the safety and effectiveness of the algorithms.

In parallel, scientists will work to develop innovative artificial pancreas systems that combine an insulin pump and a CGM system in a single device – requiring only one access point through the skin.

During the final year of the four-year project, a multinational clinical trial will compare the performance of the newly created artificial pancreas system with standard intensive insulin therapy.

Artificial Pancreas Project Featured in *Wired* Magazine

Medical journalist Dan Hurley has written an inspiring and informative article in *Wired* featuring JDRF Board member Jeffrey Brewer and his "quest to put millions of diabetics on autopilot." The story highlights how Jeffrey became "advocate-in-chief" for bringing an artificial pancreas to market following his son's diagnosis with type 1 diabetes. It also tells the story of JDRF's Artificial Pancreas Project, which was launched in 2005 thanks in large part to Jeffrey's determination and commitment. To read the article, visit www.jdrf.org/files/General_Files/APP/2010/Robotic_Pancreas.pdf.

JDRF has launched the Artificial Pancreas Project to accelerate the availability of an artificial pancreas to people with diabetes, one of the foundation's cure therapeutic pathways. The overall goal of the project is to accelerate the development, regulatory approval, health insurance coverage, and clinical acceptance of continuous glucose monitoring and artificial pancreas technology. The long-term goal is for broad patient access and a thriving competitive market for these devices and products.

For regular updates about the Artificial Pancreas Project, please visit www.artificialpancreasproject.com.