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HEALTHCARE SERIES

SPECIAL HEALTH SECTION: DIABETES

■ **Researchers are trying to create a synthetic organ that can house insulin-producing cells, sense blood-sugar levels and release the right amount of insulin.**

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Research on a bioengineered mini organ that can house insulin-producing cells, as well as

sense blood sugar to release the right amount of insulin in real time, is giving fresh hope to people living with type 1 diabetes.

Dubbed the BioHub, scientists at the Diabetes Research Institute of the University of Miami's Miller School of Medicine have been incorporating years of experimentation in related fields to create a platform that mimics the function of a healthy pancreas. If

all goes well, the BioHub could be on the market within the next decade. Clinical trials are scheduled to start next year.

"I anticipate it may take about 10 years, depending on delays and regulatory challenges," said Dr. Camillo Ricordi, the institute's director, "but we are moving in the right direction. We are

• TURN TO BIOHUB, 7HH



• BIOHUB, FROM 1HH

putting the pieces of the puzzle together to replace the pancreas.”

Type 1 diabetes, once known as juvenile diabetes, is usually diagnosed in children or adolescents, though it can develop at any age. It is a chronic autoimmune disease — in other words, the body’s immune system attacks the insulin-producing cells in the pancreas known as islets and destroys them. Islets are important because they sense blood glucose and produce the necessary amount of insulin to stabilize blood sugars. Without them, the body’s cells can starve from lack of glucose.

Though there is no cure, a person with type 1 diabetes manages the disease by taking insulin injections, a challenging balancing act because it is not always easy to know how much insulin to take. Only about 5 percent of the 25.8 million Americans with diabetes have type 1, according to the American Diabetes Association.

The less serious and far more common form of the disease, type 2, develops when the body becomes resistant to the effects of insulin or doesn’t make enough insulin. Though the BioHub is being tested only on type 1 patients, Ricordi expects the concept of developing a replacement for these important islet cells to be applicable for type 2 as well.

IMPLEMENTATION

For the BioHub to take the place of a healthy pancreas, Ricordi’s team must overcome three obstacles: find a ready supply of insulin-producing cells; be able to accept these cells without the need for antirejection drugs; and provide a

platform/site to place these new cells. In the initial phase of the clinical trials, the Miami scientists will address the housing portion of the equation.

Think of the BioHub as a home for the islet cells, a home with enough space for each cell to thrive comfortably and with a ready source of oxygen, nutrients and growth factors. Ideally, the islet cells will also have a thin coating to protect them from immune attacks. Ricordi and his team will be testing two housing types. One is a porous, sponge-like silicone about the size of a quarter. This transparent housing — which Ricordi calls “scaffolding” — is already in use for other medical conditions and is compatible with the human body.

Researchers would implant this BioHub in the omentum, a lining in the abdominal cavity that connects the stomach to other abdominal organs. The BioHub, containing islet cells, would then sense blood-sugar levels and release insulin in a real-time response.

In addition to this sponge-like platform, UM scientists will also test more natural containers, such as using a patient’s own vein within the abdomen to create a “venous sac.” And, like the silicone scaffolding, this biological sac can also house other agents to create the proper environment for the islets. This part of the experiment is a collaborative effort between scientists in Miami, their European partners in Tbilisi, Georgia, and in Edmonton, Canada.

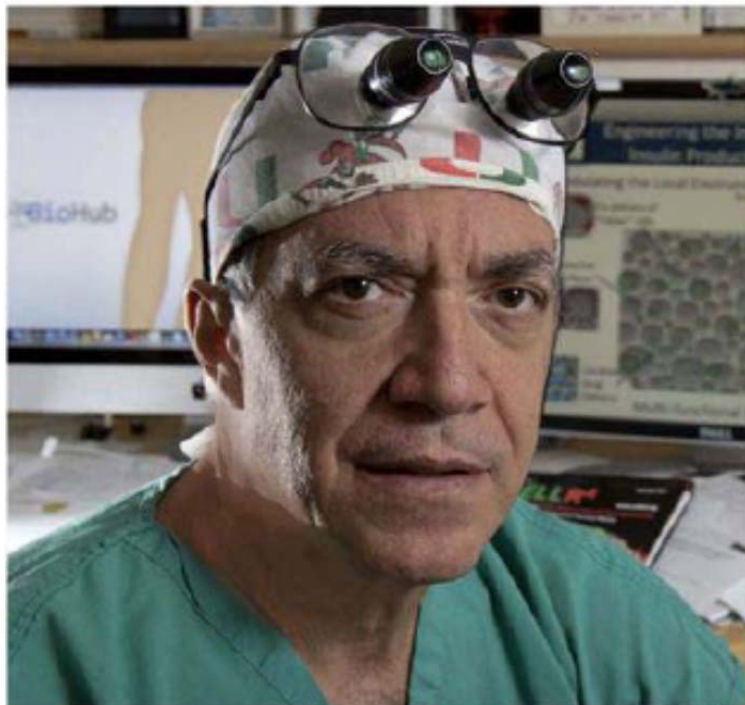
SPECIAL CELLS

Eventually, researchers hope to find various sources of islet cells to be used in the BioHub. There is no

timetable for clinical trials on this portion of the research, however. “There has been progress,” Ricordi said. “but we’re still exploring different supplies.”

Among the source possibilities: animal cells, such as those from pigs, which are very similar to human cells; and stem cells, both embryonic and adult stem cells transplanted from a patient’s own body.

Ricordi is partial to human stem cells because this reduces the chances of rejection and eliminates the need for the recipient to take antirejection drugs. Though the research using embryonic stem cells is at a more advanced stage, Ricordi is also hopeful that a collaborative experiment that trains skin cells to become insulin-producing cells will yield results.



TEAM-DRIVEN EFFORT: Dr. Camillo Ricordi is director of the University of Miami’s Diabetes Research Institute, which has separate groups working on solving issues for the BioHub.

Previous clinical trials transplanting human islet cells into the liver have shown that patients can achieve insulin independence, but this procedure has been limited to the most severe cases of diabetes. “It’s like a blood transfusion with the infusion of the cells into the organ,” Ricordi explained. “They’ve engineered the liver to become a double organ, and

we know it works well.”

Though there are still issues to be resolved in this kind of infusion, Ricordi said the BioHub can build on these latest developments in immunology, transplantation and bioengineering.

“We are using what we’ve learned through the years,” he added, calling the BioHub “a quantum leap forward.”