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Diabetes Tech: First Human BioHub Transplant a Success!

By Ginger Vieira

The Diabetes Research Institute (DRI) is making great strides in the development of their BioHub transplantable islet cell technology. After recently receiving FDA approval to move forward to Phase II of human clinical trials, the DRI and University of Miami Miller School announced the successful completion of their first human transplant of insulin-producing cells through BioHub technology.

The BioHub, a "bioengineered mini organ that will mimic the native pancreas to restore natural insulin production in people with type 1 diabetes," is the result of decades of research around clinical islet cell transplantation.

"This was the first transplant of islets on the surface of the omentum, a highly vascularized tissue covering abdominal organs, using a biologic, fully re-absorbable scaffold technique. The site is easily accessed by minimally invasive surgery, and more importantly, has the same blood supply and drainage characteristics of the pancreas – where islets are originally found before they are destroyed in type 1 diabetes," explains Camillo Ricordi, MD, director of the DRI and the Stacy Joy Goodman Professor of Surgery, Distinguished Professor of Medicine, Professor of Biomedical Engineering, Microbiology and Immunology at the University of Miami Miller School.

"This is the first tissue engineered islet transplant using a 'biodegradable scaffold' implanted on the surface of the omentum, to minimize the inflammatory reaction that is normally observed when islets are implanted in the liver or in other sites with immediate contact to the blood. Avoidance of inflammation has been shown to be important to minimize harm to the newly transplanted islets, and we are all very excited about the potential of this new clinical trial."

What are islet cells?

Islet cells are crucial to normal production on insulin in a non-diabetic. "In type 1 diabetes, the insulin-producing islets cells of the pancreas have been mistakenly destroyed by the immune system, requiring patients to manage their blood sugar levels through a daily regimen of insulin therapy," explains the press release.

"Islet transplantation has allowed some patients to live without the need for insulin injections after receiving a transplant of donor cells. Some patients who have received islet transplants at the DRI have been insulin independent for more than a decade, as DRI researchers have published."

How it works:

The technology of the BioHub begins with a "biodegradable scaffold" and relies on both the patient's own blood plasma as well as "thrombin" which is a common clinical-grade enzyme used in various types of medical technology.

> *When combined, these substances create a gel-like material that sticks to the omentum and holds*

> *the islets in place. The omentum is then folded over around the biodegradable scaffold mixture. Over time, the body will absorb the gel, leaving the islets intact, while new blood vessels are formed to provide critical oxygen and other nutrients that support the cells' survival. This pilot trial will include the immunosuppressive regimen currently used for clinical islet transplantation studies and will be limited to a small group of participants.*

"The objective of this first trial is to show that these cells can function in this new transplant site, but demonstrating safety is paramount to all of us; safety first and then effectiveness," adds Rodolfo Alejandro, MD, Professor of Medicine and director of the DRI Clinical Cell Transplant Program. "We hope that in the omentum, which is quite rich in blood vessels, vascularization is accelerated allowing more islets to survive and engraft, and that we can show that this site is both a safe and viable alternative as a transplant site on which to further the DRI BioHub projects."

The tricky part, of course, is ensuring that the islet cells survive and are not destroyed by the patient's immune system. "Currently, islet cells are infused into the liver, but many of the cells do not survive in that environment," explains the press release.

"The liver is a very simple site to access, but we have known for years that it's not the ideal site. And the liver will not accommodate a device for housing the islets," explained Dr. Alejandro.

"We have to show initially that this transplant can function and be equivalent to the liver as a site of implantation," explains Dr. Ricordi. "We will then add all the other components that will favor new blood vessel development, oxygen generation, cell protection and other agents that will allow us to reduce and eventually eliminate systemic immunosuppression, which is our ultimate goal for a biological cure."

About the Diabetes Research Institute

The Diabetes Research Institute at the University of Miami Miller School of Medicine leads the world in cure-focused research. As the largest and most comprehensive research center dedicated to curing diabetes, the DRI is aggressively working to develop a biological cure by restoring natural insulin production and normalizing blood sugar levels without imposing other risks. Researchers have already shown that transplanted islet cells allow patients to live without the need for insulin therapy. The DRI is now building upon these promising outcomes by developing the DRI BioHub and is testing various BioHub platforms in preclinical and clinical studies.