SIM (Self-generating Insulin Microdevice): encapsulated pancreatic islets for treatment of type I Diabetes Mellitus

The Challenge

Insulin-dependent diabetic mellitus (T1DM) is an autoimmune disorder resulting from destruction of insulin-producing pancreatic cells. Exogenous administration of insulin and daily tight blood glucose control are the recommended therapies to delay the progression of diabetes-associated complications and death. Nowadays, there are many different approaches from insulin pump to bioartificial pancreas. However, there are still many important drawbacks such as immunosuppression, infections, short-term therapy (limited viability of cell) and dependence of external glucose sensing.

The Market

According to WHO the number of people with diabetes is expected to rise to 592 million by 2035. In total, 8.8% of the adult population has diabetes, 5% of them have type 1 diabetes. Patients with T1DM requires daily insulin shots and constant monitoring, representing a significant lifelong cost and time requirement. As direct cost, a lifetime treatment of T1DM patient is calculated to be ~$133,695. Another important impact on the health economy is due to indirect costs, related to the chronicity of the disease such as total household income, lost workdays, bed days and missed school days to cite some examples. The social impact is calculated to be ~$289,216 per each single patient with T1DM.

The Asset

SIM (Self-generating Insulin Microdevice) represents a new innovative approach for artificial pancreas, constituted by **microencapsulation of 3D bioprinted cell islets mimicking the real effect of the own patient organ**. The current strategy focuses on implantation in skeletal muscle tissue to enhance neovascularization of the device and viability of cells. SIM will be a new efficient therapy for T1DM avoiding continuous and invasive surgical interventions for glucose sensors and electric battery replacement. It allows preventing patient's immunosuppression and, at same time, delivering the optimal blood and oxygen supply for long term therapy. The insulin release is regulated by self-physiological glucose control. We can foresee that SIM will be able to mimic the effects and actions of the patient's pancreas with a just a sole injection or implantable patch.

The asset value

The new implantable artificial pancreatic proposed will allow **long-term survival and function of transplanted cells in the host's body**. This elimination of the burden of insulin therapy will increase the quality of life of the patients and reduce significant all the direct and indirect costs associated with T1D.

- *Cost-effectiveness*. Our 3D bioprinter fabricates 80 spheroids/minutes. The cost is approximately €0.80 per spheroid.
- *Scalability.* The entire production process can be automated where the manual input from operator, and the associated errors, are minimised.
- *Versatility.* Our bioink can encapsulate different cell types such as hepatic and skeletal muscle cells.
- *Safety.* Our protocol did not require any genetic manipulation of the cells (i.e., CRISPR-cas9).
- *Consistency.* Our bio-ink formulation is consistent throughout all the development process ensuring negligible variability among different batches.

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EXCELENCIA SEVERO OCHOA

Integration of nanotechnology, biology and tissue engineering to improve pancreatic islet performance

Artificial pancreas implantable in skeletal muscle tissue

Uses

- Treatment of type I Diabetes Mellitus.
- Companion diagnostics and prognosis in vitro method.
- Different cell types can be encapsulated as hepatic and skeletal muscle cells.
- Other clinical applications, for example treatment of hepatic diseases and improvement liver function in patients in waiting list for liver transplant.

Scientific Project Leader

Prof. Javier Ramón Azcón
https://ibecbarcelona.eu/biosensors

Stage of development

TRL3 - The technology is fully validated in the laboratory and a preliminary safety test in pre-clinical model has been done. It is ready to be more extensively tested in preclinical disease models to assess efficacy in liver functions supply, biomaterial's mechanical properties and cell delivery.

Intellectual Property Status

WO2021048250A1, PCT application filed in Sept 2020, the patent application has entered National Phase in EU and US. Possibility to extend the protection to other territories.

Exploitation plan

Patent available for licensing with technical cooperation / Technical co-development

Contact

techtransfer@ibecbarcelona.eu

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