

Autonomous Type 1 Diabetes Management

Publication in "The Lancet Digital Health" of the positive results of the WP7 clinical trial with Diabeloop's integrated DBLG1 System in real life

Paris, May 15 2019 - The French company Diabeloop announced the publication in the international journal "The Lancet Digital Health" of the finalized results of the major study conducted in real life with its autonomous and personalized device DBLG1 System.

This randomized trial evaluated the safety and efficacy of the DBLG1 System in 68 people with type 1 diabetes at home, compared to sensor augmented pump therapy. The results demonstrated a significant improvement in glycemic control and a reduction of hypoglycemic risk in adults with type 1 diabetes while using the closed-loop hybrid system. This reinforces integrating this device into routine medical practice.

The publication in the leading international medical journal, "The Lancet Digital Health", is the first of its kind with 68 patients enrolled in a multicenter, randomized, 12-week controlled trial. Patients had type 1 diabetes for at least two years and had been treated with an external insulin pump for at least 6 months. Their glycated haemoglobin (or HbA1c), a reflection of blood glucose, was less than or equal to 10%. In this cross-over trial, patients spent 12 weeks successively with a conventional open-loop system (external insulin pump with continuous glucose measurement) and 12 weeks with Diabeloop's DBGL1 closed-loop hybrid system. DBGL1 System combines an insulin micro-pump, a glucose sensor to measure blood glucose continuously and a control algorithm.

The aim of the study was to evaluate whether Diabeloop's DBLG1 System regulation algorithm allows for a higher glycemic control than usual insulin pump therapy over a 12-week period. The primary endpoint of the study was the percentage of time the patient spent in the target range (70 - 180 mg / dL) as measured by the glucose sensor. The results showed that the proportion of time during which the glucose concentration was in the target was significantly higher in the DBGL1 group (68.5%) than in the group treated with a conventional external pump (59.4%). This confirms the positive results observed in hospitals.

Main outcomes:

- 68.5% time spent in the target glucose range meaning a **10 point increase in the time spent in the target glucose range**
- Decrease by 50% of time spent in hypoglycaemia (<0.7 g / l), ie a gain of more than **30 minutes less per day in hypoglycaemia**
- No adverse metabolic side effects have been linked to poor algorithm decisions
- A reliable closed-loop system that was functional for more than 84% of the time in a home setting for 12 weeks

The study was conducted at centers with little experience in hybrid closed-loop systems, therefore indicating the simplicity of use of the DBLG1 System.

A summary of the objectives of the study and its results is available in this [video](#)

"These results support the use of closed-loop technology with appropriate patient support in adults with type 1 diabetes. This is the first study of this magnitude over long-term, real-life conditions. This innovation is particularly interesting for patients with high HbA1c," says Professor Pierre-Yves Benhamou, head of the endocrinology department at the University Hospital of Grenoble and principal investigator of the WP7 trial.

For patients, Diabeloop's hybrid closed-loop system also increases the quality of life by reducing the daily constraints associated with dozens of calculations and therapeutic decisions to be taken in order to control their blood sugar level. The machine-learning algorithm built into the DBGL1 System is indeed able to anticipate the evolution of the patient's blood glucose or to correct significant variations to deliver the correct dose of insulin.

Erik Huneker, founder and co-CEO of Diabeloop says he is honored with the publication in "The Lancet Digital Health" and adds "since the WP7 clinical trials two years ago, we have continued to further improve the personalization of the response of the algorithm to situations encountered by patients. We are testing these versions in silico and hope to deploy them soon with even more significant results."

Clinical trials in children in Belgium and France in 2019

Following these results, Diabeloop is looking to adapt its artificial pancreas project to juvenile diabetes and thus improve the quality of life for each child in the short term and the long-term. A study will be conducted in two centers in France and one in Belgium. The goal is to include around 20 children who will be followed for 6 weeks.

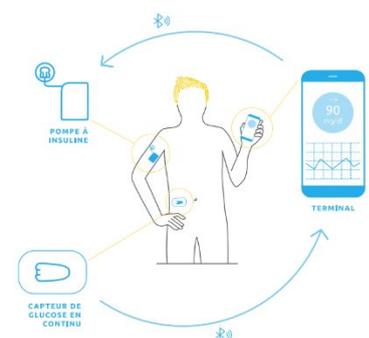
About DBLG1 System

The DBLG1 System is based on a self-learning algorithm hosted in a dedicated handset and associated with a continuous glucose measurement system and an insulin patch pump.

This breakthrough technological innovation automates almost completely the treatment of type 1 diabetes by reproducing the functions of the pancreas destroyed by the disease..

DBLG1 calculates the amount of insulin required and automatically adjusts insulin delivery. Following clinical trials, DBLG1 from Diabeloop was CE marked in November 2018 in adults.

The device will be released gradually in 2019 in reference centers in France. In parallel, Diabeloop continues to work on the request for



FONCTIONNEMENT DU DBLG1 SYSTEM
© Diabeloop 2018

support of the device by the Social Security to make it accessible to the greatest number.

About type 1 diabetes

Type 1 diabetes is an autoimmune disease that destroys pancreatic β -cells, which causes the pancreas to become totally incapacitated and insulin-producing. The only treatment is insulin delivery for life. Patients should evaluate their blood glucose and calculate several times a day the impact of their activities, their meals and the dose of insulin needed to inject several times a day. It is difficult, despite the progress made, to obtain a perfect and prolonged control of blood sugar.

Type 1 diabetes and its treatments have a significant impact on quality of life, personal, family and work. Continuous subcutaneous administration of rapid insulin analog with an insulin pump has been an important advance, the results nevertheless remaining imperfect. The possibilities of current technical improvements are based on intelligent systems of continuous insulin delivery, able to automatically correct episodes of glycemic variability, based on predetermined algorithms.

About Diabeloop

Created in 2015 in Grenoble by Erik Huneker and Dr. Charpentier, Diabeloop and CEA-Leti are linked within a joint research laboratory to accelerate the development of the DBLG1 device. The company is co-managed by Marc Julien and Erik Huneker and had a staff of 50 in April 2019. In order to develop and bring the DBLG1 System to market, the company made a first round of funding of 13.5 million euros in mid-2017, a second round of funding, to support international commercialization and an ambitious R&D roadmap, is in progress.

Press contacts:

Diabeloop

Stéphanie Jégu - stephanie.jegu@diabeloop.fr

PRPA

Isabelle Closet – isabelle.closet@prpa.fr – 01 77 35 60 95 / 06 28 01 19 76