The role of Bluetooth and AI in an artificial pancreas

Wireless technology and machine learning combined in an artificial pancreas help type one diabetics live unimpeded, explains **Thomas Søderholm**

In 2003, biological physicist Philip Nelson wrote: "At the dawn of the 20th century, it was already clear that, chemically speaking, you and I are not much different from cans of soup. And yet we can do many complex and even fun things we do not usually see cans of soup doing."

An example of the engineering complexity of the human body is the pancreas. This organ, which primitive medicine assumed was little more than a shock absorber to protect the stomach from the spine, is the body's factory for a range of digestive enzymes as well as insulin and glucagon, which are the hormones that ensure our brains and bodies have a steady supply of energy. It is near enough as fundamental to life as a heart that beats; just ask any of the estimated nine million people across the globe who suffer from type one diabetes.

This is a chronic disease that renders the insulin-producing cells in the pancreas ineffective. Left unchecked, the disease can damage the heart, blood vessels, eyes, kidneys and nerves, and could result in coma and death.

A century ago, before the role of insulin was understood, people with type 1 diabetes had a lifespan of little more than a year or two. With a deeper understanding of the disease and advances in medical technology, today's prognosis is considerably brighter, but living with diabetes remains difficult. It requires the individual to measure and control their blood glucose level by taking insulin either by subcutaneous injection or through an insulin infusion pump. This ritual is required often up to four or five times a day, every day, for the rest of the person's life.

Today, medical and wireless technology innovation promise a much easier life for sufferers in the form of the 'artificial pancreas'.

The art in artificial

Unlike prostheses that substitute for other parts of the body that are either missing or defective, limbs, arteries, heart valves, eyes, or teeth for example, the artificial pancreas doesn't physically replace the faulty organ, but rather mimics it from outside the body.

The artificial pancreas' closed-loop system is made up of two devices: an insulin infusion pump; and a continuous glucose monitor (CGM). The infusion pump automatically administers insulin according to an algorithm determined by the wearer's physician, based on medical history and lifestyle.

Insulin is gradually delivered via a compact cannula to prevent the medication pooling under the skin.

The CGM samples the wearer's interstitial fluid (fluid in the spaces between cells) every few minutes using a minimally-invasive subcutaneous needle sensor. The glucose level in the interstitial fluid is a good proxy for the glucose level in the blood (although changes do lag by approximately 15 minutes). The CGM relays the glucose data to the pump using Bluetooth Low Energy (LE) wireless connectivity.

When the CGM indicates the glucose is high, the pump notifies the user. The patient must then manually operate the pump to administer more insulin to compensate for the peak. When blood glucose levels dip below a preset threshold however, the pump automatically stops administering insulin and warns the user to raise their glucose levels by consuming carbohydrates. This is a vital function because persistently low glucose levels (hypoglycemia) can result in coma. Once glucose levels recover, the pump automatically starts to deliver insulin again.

The user is responsible for instructing the pump to administer additional 'boluses' of insulin when they eat meals. The diabetic user calculates the amount of carbohydrates that are in their food, and the pump calculates and delivers the insulin required to deal with the associated glucose rise.

The CGM sensor data is a vital source of information for medical staff. The pump stores the data from the CGM and periodically transmits it via a Bluetooth LE link to the user's smartphone (which typically hosts an app that supports review and transmission of the data and/or notification for family and friends of any potential medical issues). Bluetooth LE is interoperable with most of the world's smartphones. Chips from major Bluetooth LE vendors feature services such as 128-bit advanced encryption standard (AES) cypher block chaining message authentication mode and other security features to protect the patient's medical information as it is sent across the wireless link.

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From the smartphone, the data can be transmitted to the cloud via the cell network, which is robust, secure and reliable. A remote physician can review changes in glucose levels and use this record to adjust the patient's long-term insulin management strategy.

Advanced intelligence

While the contemporary artificial pancreas is impressive, it falls short of the performance of the real organ. Mother nature has had plenty of time to evolve the pancreas and has done an admirable job. Engineers must meet much shorter project deadlines, but are working hard to close the gap.

Future developments for the artificial pancreas include the infusion pump automatically revising the volume of insulin the patient receives when transient glucose spikes occur and are detected by the CGM, without patient intervention. Early models with this feature are already with the US Food and Drug Administration and other authorities for regulatory consideration.

As infusion pumps become even more sophisticated, they will be able to incorporate data sent wirelessly from advanced wearable devices to account for factors such as motion, sweat levels, body temperature and other lifestyle signifiers. Physiological parameters such as the patient's overall health, heart rate, stress levels and sleep patterns, in addition to carbohydrate consumption, all influence blood glucose levels.

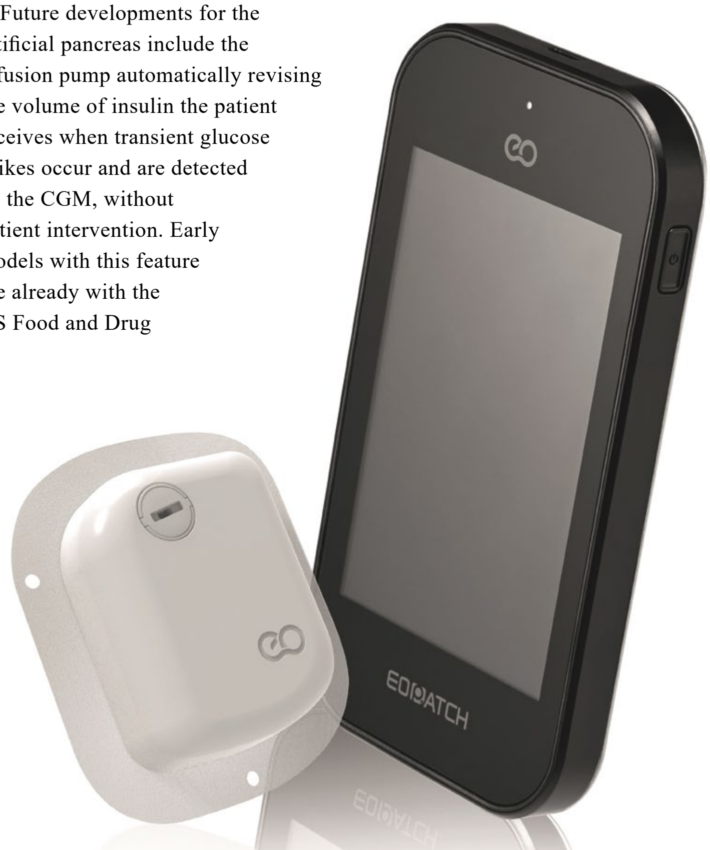
Further development will include the incorporation of compact and low power cellular IoT (NB-IoT/LTE-M) technology into the infusion pumps. Cellular IoT eliminates the need for a smartphone to deliver data securely and reliably to the cloud. Cellular IoT will also make it easier to leverage the power of machine learning, a subset of AI, to adapt the infusion pump's glucose delivery algorithm.

Cellular IoT offers a secure, bi-directional and long-range wireless connection to the cloud without the need of a smartphone acting as a gateway. Data from the patient's CGM and other physiological sensors will be sent over the cellular IoT link anywhere there is cellular coverage. Using powerful cloud servers equipped with machine learning, the data can be used to precisely adapt and optimise the insulin delivery algorithm. The modified algorithm would then reprogramme the infusion pump over the air.

The benefits of continuous adaptation will be significant. If the level of blood glucose can be kept as stable as possible over the long term using a machine learning-assisted artificial pancreas it will reduce the damaging cumulative effects of transient elevated glucose episodes. This not only extends patient lifespan, but also increases their quality of life. Tomorrow's artificial pancreas will also lower hospital admissions.

The key to future enhancement in diabetes care lies in an artificial pancreas using machine learning supported by cellular IoT. That in turn demands powerful, compact and highly efficient wireless chips.

As a result, companies are collaborating, bringing expertise together. For example, Nordic Semiconductor is collaborating with US-based machine learning specialist Edge Impulse to deliver advances in artificial pancreas design. ❑



In the EOPatch insulin management systems, by Korea-based EOFlow, Nordic Semiconductor's Bluetooth LE wireless connectivity sends data to a smartphone

About the author

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