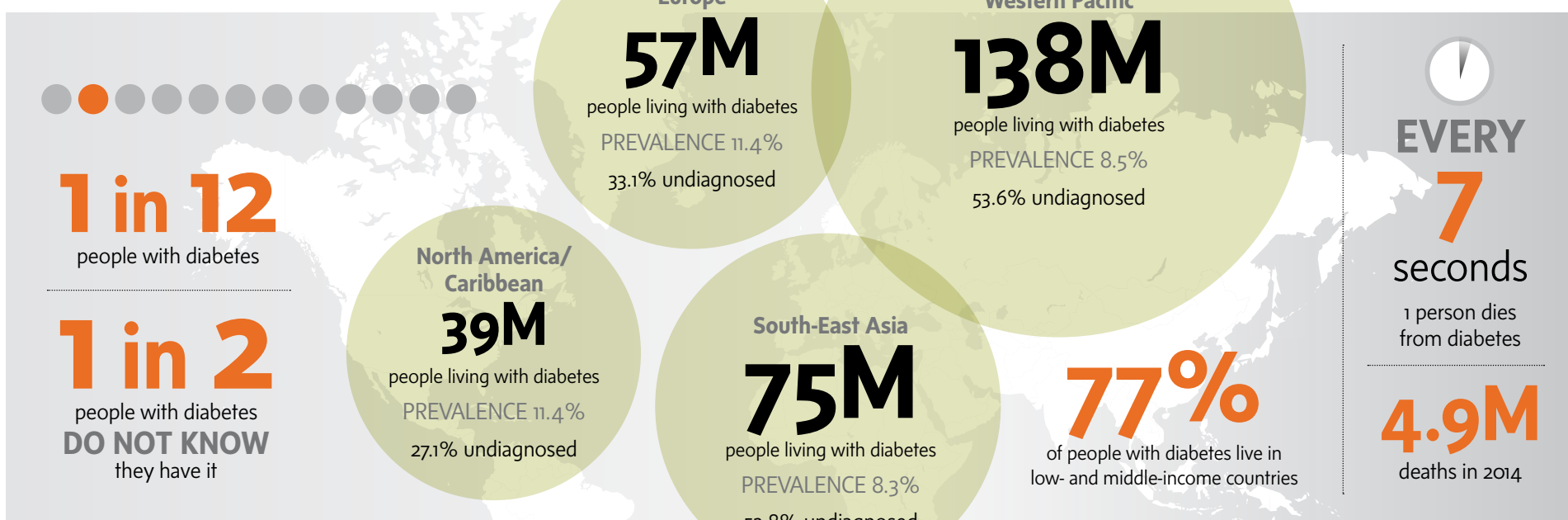


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Diabetes

WORLDVIEW



New invention aims to provide convenience and comfort for those living with diabetes

The International Diabetes Federation (IDF) expects the number of people living with diabetes to rise from 387 million in 2014 to 592 million by 2035, which will dramatically increase global demand for treatment and control of the disease.

Most people with diabetes control their blood glucose level with insulin. They need to regularly test their blood sugar during the day, and the standard test is finger pricking to draw blood, which is then applied to a test strip that provides a result.

But finger pricking, even with spring-

loaded lancing devices, can be painful and stressful. Now researchers at the University of Calgary are developing what they believe could be a significant new method of blood sugar testing using a device which they say mimics a mosquito and is virtually undetectable as it draws blood.

Called the eMosquito – for electronic mosquito – the device could be in clinical trials within a year, according to Martin Mintchev, a director of M Pharmaceutical Inc. (MQ-CSE), a Vancouver-based company that is collaborating with the inventors of the

new device to take it through clinical trials and regulatory approvals.

"This could be an important breakthrough for people with diabetes," says Dr. Mintchev. "The eMosquito is a device that will automatically monitor their blood sugar levels throughout the day with less discomfort and stress than traditional methods. In addition, blood sugar data can be sent wirelessly to users' smartphones and/or physicians, eliminating the need to carry bulky testing hardware."

He points out that the IDF estimates that diabetes caused at least US\$612-

billion in health expenditure in 2014 – 11 per cent of total spending on adults globally.

According to industry analysts including Frost & Sullivan, BMI Espicom and IEK Industrial Technology Research Institute, the value of the global market for blood glucose measuring devices is expected to grow from an estimated US\$845-billion in 2014 to US\$897-billion in 2016.

"The care and treatment of people with diabetes is a potentially huge market," adds Dr. Mintchev. "We believe this will mean growing demand for new and more convenient ways of testing blood sugar levels, which is why we are supporting the development of the eMosquito."

M Pharmaceutical Inc. is pursuing interests in pharmaceuticals and biomedical devices. It signed an arm's-

length binding letter of intent with M Diagnostics Inc., a Calgary company that holds the rights to the eMosquito, which was developed by the shareholders of M Diagnostics Inc., Dr. Martin Mintchev, Dr. Orly Yadid-Pecht and Mr. Joseph Wang at the University of Calgary.

The letter of intent provides for the acquisition of all the rights to the eMosquito technology.

For more information on the eMosquito and M Pharmaceutical Inc., please visit the company website at www.m-pharma.ca.

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INNOVATION

Mosquito bite provided inspiration for wearable blood sugar test device

Like most scientists, much of Martin Mintchev's work is motivated by "what-if" questions. As a biomedical engineer, it's only natural that his search for solutions to complex problems would focus on how to combine technology and medicine to develop new ways to help people with chronic illnesses like diabetes.

With that in mind, his question became: what if we could develop a wearable electronic microsystem that can automatically and sequentially activate and control miniature needles from a given set, the pricks of which would be hardly discernable, yet each of them would draw enough blood to test a user's glucose level?

'Can't be done' was the general response 10 years ago when Dr. Mintchev and fellow researchers began re-exploring an existing idea to develop a tool that would mimic nature, specifically a mosquito, to draw blood for medical testing. They spent several years on the project and advanced it in the laboratory to a first generation device, but it wasn't practical enough to take it further. The materials available at the time simply didn't match their needs, and the size of the prototype was similar to a deck of cards, which made it impractical to wear.

Then technology began to catch up. The emergence of shape memory alloys and further miniaturization of measuring instruments meant that a commercially viable and conveniently wearable electronic mosquito to provide diabetics with a new way of monitoring blood sugar was a distinct possibility – eMosquito became a reality.

Dr. Mintchev is currently a professor of Electrical and Computer Engineering at the University of Calgary and an adjunct professor of surgery at the University of Alberta in Edmonton. He is also a registered professional engineer in Alberta. He and two colleagues at the University of Calgary, Dr. Orly Yadid-Pecht and Mr. Joseph Wang, filed a patent for their invention last November and are now collaborating with M Pharmaceutical Inc. of Vancouver to conduct clinical trials and facilitate the regulatory approvals of the device.

Dr. Mintchev believes pilot clinical trials could begin within a year. In the meantime, the team will focus on building 10 to 15 prototypes to help perfect the technique and functioning of the device.

A key breakthrough in the quest for a viable eMosquito came with the evolution of new materials known as shape memory alloys.

"In our device, the shape memory alloy is a metal-like wire, which in a relaxed state is flexible and not rigid at

"As soon as the needle reaches a capillary, it retracts. In most cases, capillaries are slightly closer to the skin surface than the nerve endings, so users should feel virtually nothing."

Martin Mintchev

is a professor of Electrical and Computer Engineering at the University of Calgary



eMosquito uses the latest advances in technology to mimic nature – specifically the mosquito. ISTOCKPHOTO.COM

all," explains Dr. Mintchev. "But when you pass relatively small electrical current through it, it becomes tense and can exert enough force to control a miniature needle to penetrate the skin and extract a small whole blood sample. This creates the unique opportunity to design really flat, in-plane needle actuators controlled by infrared-power electronics that can be easily wearable by the patient, initially in the form of a small cuff, and eventually, as the technology matures, as a Band-Aid-like patch."

Contained in a cuff that fits on the wrist or ankle, the present version of the eMosquito is controlled by its built-in electronics and powered by a small, flat battery. The device is programmed so that each of the needles from the set "bites" at a pre-determined time.

"The user is not aware of the exact moment of biting – much like an actual mosquito bite," says Dr. Mintchev. "As soon as the needle reaches a capillary, it retracts. In most cases, capillaries are slightly closer to the skin surface than the nerve endings, so users should feel virtually nothing, but the capillary pressure will be sufficient for a small whole blood sample to appear at the base of the bite on the skin and a built-in standard glucose sensing strip will detect the glucose level."

The electronics for measuring the

glucose level from the extracted whole blood sample is the same as that in commonly used present-day finger pricking devices, but a lot smaller in size. Each needle from a given set only "bites" once, after which the electronic control moves to another needle of the same set, which bites in a slightly different location on the skin when it's time for the next test. The process is repeated as often as necessary, until all needles in a given set are exhausted. At the end of the day, the cartridge set with the cells that contain the needles is replaced with a new one.

The timing of bites can be tailored to each user's needs and monitored if necessary by a medical professional, care giver or parent.

"More frequent blood glucose tests during the day reduce the risk of diabetes-related health problems," says Dr. Mintchev. "For all type 1 diabetes patients and about 20 per cent of type 2 patients – those who need insulin therapy – at least four tests a day are required."

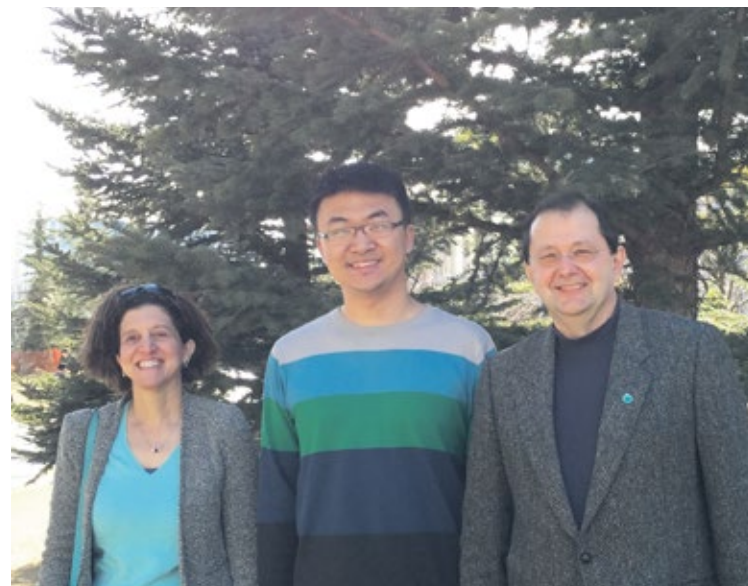
He believes an automated and regular testing system like the eMosquito will not only be more convenient and comfortable for users, but will also help them better understand their blood glucose trends.

Initially, insulin will continue to be administered as it is now by injection or infusion pump, but future generations of the eMosquito could include remote electronic control capabilities to connect it to a wearable transdermal insulin infusion pump that would automatically provide the right dose of insulin based on the results of each bite. Thus, two small, wearable and minimally inconvenient electronic "patches" (one to test blood glucose and the other to deliver the necessary insulin) can serve as an autonomous external artificial pancreas.

While the cost of the device if it is commercialized has not yet been decided, Dr. Mintchev believes it will be acceptable to the market because the materials from which it is made are relatively inexpensive.

"The application of shape memory alloy-based actuation creates the possibility that the cost of each individual eMosquito cell will be comparable to the cost of a single strip for glucose testing at the moment," he says. "The cell itself will be connected to a standard glucose-sensing strip. The electronics and the reporting will be a one-time expense similar to the existing glucose monitoring devices associated with finger pricking. They are similar electronic devices."

But the advantage of eMosquito, he adds, is convenience, regularity of testing and less stress and physical pain for users.



The three inventors of the e-Mosquito. From left, Dr. Orly Yadid-Pecht, Mr. Joseph Wang and Dr. Martin Mintchev. SUPPLIED

FACT CHECK

What is diabetes?

Diabetes is a chronic disease that occurs when the pancreas is no longer able to make insulin or when the body cannot make good use of the insulin it produces. Insulin is a hormone made by the pancreas that lets glucose from the food we eat pass from the blood stream into the cells in the body to produce energy. All carbohydrate foods are broken down into glucose in the blood. Insulin helps glucose get into the cells.

Not being able to produce insulin or use it effectively leads to raised glucose levels in the blood, known as hyperglycaemia. Over time, high glucose levels are associated with damage to the body and failure of various organs and tissues.

THERE ARE THREE MAIN TYPES OF DIABETES:

Type 1 diabetes used to be called juvenile-onset diabetes. It is usually caused by an auto-immune reaction where the body's defence system attacks the cells that produce insulin. People with this form of diabetes need injections of insulin every day in order to control the levels of glucose in their blood. If people with type 1 diabetes do not have access to insulin, they will die.

Type 2 diabetes used to be called non-insulin dependent diabetes or adult-onset diabetes and accounts for at least 90 per cent of all cases of diabetes. It is characterised by insulin resistance and relative insulin deficiency, either or both of which may be present at the time diabetes is diagnosed. People with type 2 diabetes can often initially manage their condition through exercise and diet. However, over time, most people will require oral drugs and/or insulin.

Both type 1 and type 2 diabetes are serious. There is no such thing as mild diabetes.

Gestational diabetes (GDM) is a form of diabetes consisting of high blood glucose levels during pregnancy. It develops in one in 25 pregnancies worldwide and is associated with complications to both mother and baby. GDM usually disappears after pregnancy, but women with GDM and their children are at an increased risk of developing type 2 diabetes later in life. Maintaining blood glucose levels, blood pressure and cholesterol at or close to normal can help delay or prevent diabetes complications. Therefore, people with diabetes need regular monitoring.

Source: International Diabetes Federation www.idf.org