

## The first 'artificial pancreas' systems are coming to market

Mike Feibus, Special for USA Today 8:04 a.m. ET May 2, 2017

The first so-called artificial pancreas systems – wearable devices that take charge of the crucial process of measuring glucose levels and delivering precise doses of insulin – are now beginning to come to market.

That's welcome news for the nation's 30 million diabetics, who stand not only to get some relief from the seemingly incessant stream of lancets, test strips and syringes, but also to stay healthier. That's because an artificial pancreas can keep the disease on a tighter leash than they can, by testing more frequently and delivering more precise insulin doses.

That's not only important for patients, but could ease strains on the nation's healthcare system.

This spring, Medtronic became the first supplier out of the gate when it began outfitting a pre-selected pool of type 1 diabetes patients with its new MiniMed 670G. Once that group is trained and equipped – probably by midyear – Medtronic expects to make the device more widely available.

Several efforts – including startup Bigfoot Biomedical, Insulet and a partnership between Dexcom, Tandem and TypeZero – are hot on Medtronic's heels, with active studies now underway and plans to go to market late this year or in 2018.

Though the term artificial pancreas is widely used, medical professionals tend to steer clear because some patients hear it and think they're in for an organ transplant. They're not. An artificial pancreas doesn't replace the actual organ. Devices aren't implanted or surgically attached. Moreover, they only take over one of the organ's digestive responsibilities: that is,

regulating glucose levels.

[ArtificialFig01.jpg]

Caption: Medtronic's Minimed diabetes treatment product. (Photo: Medtronic)

Those in healthcare prefer the term "closed-loop systems," so called because they monitor glucose levels, employ artificial intelligence to make dosing decisions and deliver insulin – all without human intervention. Systems today are "hybrid closed-loop systems," because they require some intervention, usually for challenging situations like mealtime and exercise. Researchers hope one day to overcome obstacles and deliver fully closed-loop systems.

Users find hybrid closed-loop systems freeing nonetheless. Teens with diabetes, for instance, can spend the night at a friend's home because their parents don't need to wake them up to test glucose levels in the middle of the night. As well, their parents find they get to enjoy a full, uninterrupted night's sleep.

Artificial pancreas systems aren't an option for most diabetics, however. Efforts today focus on treating type 1 diabetics, whose pancreas produces little or no insulin. Type 1 patients make up no more than 10% of all diabetics.

For the more common type 2 diabetics, who develop a resistance to insulin over time, the first line of defense is to learn what triggers their condition and treat the disease with diet, exercise and other lifestyle modifications. That may or may not involve therapies like insulin injections. An artificial pancreas may be an option for type 2 diabetics whose condition has deteriorated to the point they need intense monitoring and intervention.

Diabetics who may not be eligible for an artificial pancreas system, take heed: there are plenty of new apps, wearables and management programs being developed to make care easier and more painless. I've seen lots of new products and programs in recent months and can point out two here that hit home for me. To be clear, I'm not diabetic. I just really hate

needles.

[ArtificialFig02.png]

Caption: Insulet Corp.'s Omnipod diabetes delivery system. (Photo: Insulet Corp.)

The first is a wrist-worn glucometer from French startup PKvitality. The device, called K'Track, doesn't actually draw blood. Rather, it checks glucose levels with micro-needles that imperceptibly sample what's known as interstitial fluid just under the skin.

As a wrist-worn device, K'Track is a bit oversized, even by today's chunky-watch standards. But it gets the job done, surreptitiously and – most importantly – painlessly. The company is currently pursuing regulatory clearance in Europe, and hopes to target the U.S. next.

The second is a pain-free, push-button blood-draw device called TAP from startup Seventh Sense Biosystems. Seventh Sense, which boasts investment from healthcare heavyweights like LabCorp and Siemens, just received FDA clearance for TAP to be used in lab settings. The company hopes to make TAP available for home use in the near future.

[ArtificialFig03.jpg]

Caption: PKVitality's K'Track glucose monitoring system resembles an oversized watch. (Photo: Handout, PKVitality)

I saw both K'Track and TAP first-hand at the big electronics trade show CES in January. In fact, I agreed to have TAP draw my blood on-stage at the Digital Health Summit there. So I can tell you first-hand that a TAP blood draw is absolutely pain free.

For those who find themselves to be candidates for an artificial pancreas, the experience stands to be far more life-changing than simply eliminating the discomfort of finger-prick tests. Indeed, an artificial pancreas can take charge of care. And one day they may have the luxury of being squeamish about needles, too.

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PKvitality: <http://www.pkvitality.com/>

K'Track: <http://www.pkvitality.com/ktrack-glucose/>

Seventh Sense Biosystems:

<http://www.7sbio.com/>

TAP: <http://www.7sbio.com/products/>