Graphwear Closes $20.5M Series B for A Needle-free, Nanotech-powered Glucose Monitor

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GraphWear, a company pursuing needle-free approaches to glucose monitoring, has closed a $20.5 million Series B round. This Series B round is a vote of confidence by investors in GraphWear's approach: to monitor key metrics in the body, like glucose, without breaking the skin at all.

GraphWear Technologies was founded in 2015 by Rajatesh Gudibande and Saurabh Radhakrishnan, who had both completed master's degrees in nanotechnology at the University of Pennsylvania. Specifically, GraphWear is developing a skin-surface-level wearable made of graphene (more on this material later). The sensor is small, about the size of an Apple Watch — but the key piece of technology is actually housed on the bottom. It's a thin slice of graphene that fits onto the back of the watch, or onto a sticker that can be worn on the abdomen.

This Series B round, says Gudibande, will be focused on helping the company build upon previous validation studies of the wearable, completing a pivotal trial and submitting for FDA clearance. The round was led by Mayfield, with participation from MissionBio Capital, Builders VC and VSC Ventures.

"The Holy Grail problem has been: can you really know what is happening in your blood without using things to prick your skin and draw blood out," says Ursheet Parikh the co-leader of Mayfield's engineering biology investment practice. "We think GraphWear has made progress and is likely to be one of the first companies to actually bring a product that can get to hundreds of millions of people."

Continuous glucose monitoring has been a recent push within the diabetes community. There have been several continuous glucose monitors approved in recent years, like the FreeStyle Libre, approved by the FDA in 2017. That device still uses a subcutaneous filament on an arm patch to measure glucose levels.

These devices have clear upsides for people with Type I diabetes (people whose bodies make little or no insulin). That's about 1.6 million people in the U.S. alone. The American Diabetes Association notes that most people who regularly inject insulin "should be encouraged" to use self-monitoring glucose technologies, including continuous glucose monitors, in its 2020 guidelines.

As for people with Type II diabetes (about 34 million Americans), or for people who don't regularly inject insulin, there's a bit more debate. Some argue that regularly monitoring glucose (which is what continuous glucose monitors do) isn't worth it for these populations. For example one 2017 JAMA Internal Medicine study found that routine self-monitoring of glucose didn't lead people to improve their A1c levels (a key diabetes biomarker) after one year. That study, though, evaluated people who regularly used finger-stick tests, rather than non-invasive continuous glucose monitors.

Still, the American Diabetes Association notes that, if used properly, continuous glucose monitors in conjunction with insulin therapy, can be useful tools for these people as well.

GraphWear's sensor takes a nanotechnology-based approach to continuous glucose monitoring. And, unlike other continuous glucose monitors, which may require a small retractable filament or finger sticks to evaluate blood glucose, the device doesn't break the skin at all, says Gudibande.

"The graphene has an electric field that drags the molecules up," Gudibande explains.

"You're talking about about 200 molecules," he continues. "It then 'tastes' it, converts it to an electrical signal, and then transports via Bluetooth to your phone that can chart and display glucose values continuously."

Note that these sensors are actually measuring the glucose present in interstitial fluid, not the glucose present in blood. However, there's evidence glucose measured from the interstitial fluid "correlates well with plasma glucose", per the American Diabetes Association's 2020 guidelines, so measurements taken this way are still clinically relevant for people with diabetes. Gudibande adds, "our own empirical clinical data suggests the same."

GraphWear has already completed one feasibility study for the wearable sensor on 40

patients with both Type I and Type II diabetes. They tested the device's glucose monitoring against glucose measures collected from venous blood draws. Results have not yet been released. However, Gudibande says that GraphWear's accuracy was "comparable" to that of the traditional sensor.

Glucose monitoring aside, another big picture element to consider when it comes to GraphWear is the material the sensor is made of: graphene.

Graphene is a single-atom thin carbon sheet. It happens to be an exceptional conductor of electricity, and is strong, light and flexible. Since graphene was discovered in 2004, the material has generated a lot of hype — it was supposed to be the next silicon, though that hasn't quite happened yet.

Still, the U.K., China and the EU are investing heavily in production of graphene at an industrial scale. And there are some graphene products leaking on the market already (it's in bikes, shoes, sensors and tennis rackets, to name a few applications highlighted in a 2019 review paper).

GraphWear can keep the graphene used in its sensors "pristine," says Gudibande, which allows it to be highly sensitive to glucose molecules that it may encounter. The company, says Parikh, can also manufacture the material at scale, and is developing new applications of nanotechnology that could be useful beyond sensing glucose. Specifically, the team has patented a way to use polarized fluids as transistors.

"If your glucose molecules are on the skin, it becomes like a transient transistor that shows up," says Parikh. "That is a new class of transistor, and that's a fundamental innovation."

The glucose monitoring, though, is a smart first step for the company, because there's a decently clear pathway to approval. If the company's upcoming pivotal trial demonstrates that it's similar to other continuous glucose monitors it could pursue FDA 510(k) clearance. Though, as Gudibande acknowledges, there could be some unforeseen pitfalls. For instance, it's possible that GraphWear's noninvasive approach could put it in a class of its own.

"So there's a risk to that, of whether we will be 510(k)," Gudibande says. "But the process for that will be anywhere from six to 14 months. Our goal is to get through the trials and submit

to the regulatory body.”

If GraphWear can deliver on measuring other biomolecules using its graphene platform, they could use the platform to detect other molecules or continuously monitor what’s going on inside the body. This Series B round, though, will be focused on delivering the first step: a clinically evaluated, graphene-based sensor.

Read the original article on TechCrunch.