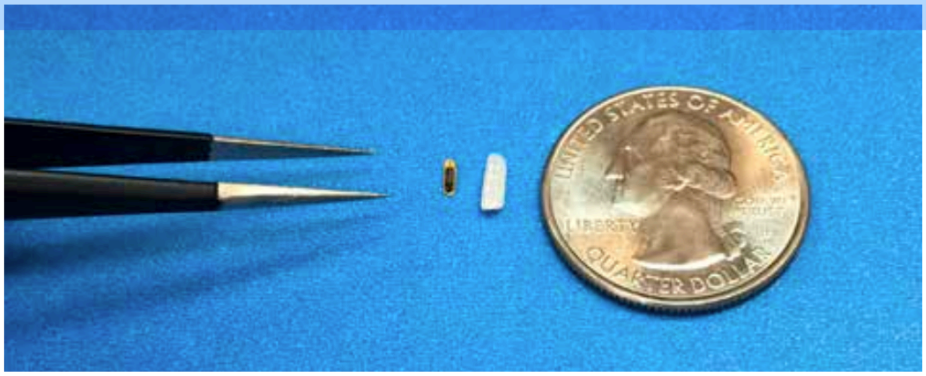

Injectsense Takes RPM to Ophthalmology and Beyond

Start-up Injectsense has an ultraminiature, MEMS-based sensor technology for remote patient monitoring that can be injected into the eye or other tissues, or integrated with an implantable device, and can be configured to measure a variety of parameters.

▶ **Mary Thompson**

Remote patient monitoring (RPM) is receiving a lot of attention at the moment due to the COVID-19 pandemic and the search for safer, cost-effective ways to remotely monitor patients—both those with chronic and acute conditions—from their homes or at the hospital bedside. (*See "Remote Patient Monitoring Enters a New Era,"* MedTech Strategist, *June 22, 2020.*) A variety of technologies and form factors are being developed for RPM, ranging from wrist-worn wearables and body-worn biostickers to injectable/implantable sensors, and sensors that integrate with a smartphone. Although wearables have been top of mind of late, particularly since the release of **Apple Inc.**'s ECG-enabled smart watch, there is room for numerous approaches as the RPM market evolves, with some form factors better suited for particular clinical applications than others. (*See "Apple's New ECG-Enabled Watch: Gizmo or Game Changer?"* MedTech Strategist, *September 28, 2018 and "The Apple Watch Arrhythmia Monitoring Debate,"* MedTech Strategist, *June 27, 2019.*)

Implantable sensors have not (yet) captured widespread attention, but some observers believe they represent the future of the RPM field, whether as stand-alone devices or as part of an implantable therapeutic device. Implantables are particularly well-suited to specific applications that require accurate, continuous monitoring of internal processes.

Some of the earliest implantable sensors were designed for cardiovascular applications. These include sensors used to monitor intracardiac pressure in heart failure patients, an application targeted by CardioMEMS with its groundbreaking pulmonary artery pressure monitor (now part of **Abbott Laboratories Inc.**), and more recently by start-up **Vectorious Medical Technologies Ltd.** with the *V-LAP* implantable left atrial pressure monitoring system. (*See "Vectorious Medical: Guiding Heart Failure Treatment with an In-Heart Left Atrial Pressure Monitor,"* MedTech Strategist, *July 25, 2019.*) There are also several long-term implantable ECG sensors now available that are designed to detect heart arrhythmias (from **Medtronic plc**, Abbott Laboratories, and **Boston Scientific Corp.**) And an implantable continuous glucose monitoring (CGM) sensor is now available for people with diabetes—the *Eversense* from **Senseonics Inc.** (*See "CGM on the Upswing: A Three-Month Implantable Enters the Fray,"* MedTech Strategist, *September 14, 2018.*) Moreover, implantable sensors are gaining ground in orthopedics, driven by regulatory and reimbursement changes wrought by the COVID-19 pandemic. (*See "Smart Orthopedic Implants' Moment to Shine," this issue.*)

Ophthalmology is another prime target for an implantable sensor, and start-up **Injectsense Inc.** has an ultraminiature sensor platform that it believes is the ideal form factor for use inside the eye. Founded in 2014, with offices in Emeryville, CA, and Minneapolis, MN, Injectsense has developed a tiny sensor—smaller than a grain of rice—that is injected into the vitreous space in the eye. The sensor currently measures pressure, but it can be configured to measure a variety of other parameters as well, including temperature, flow, motion, and oxygen saturation, according to Ariel Cao, Injectsense CEO and co-founder. The company's initial target market is remote monitoring of intraocular pressure (IOP) in glaucoma patients, a common parameter that is an indicator of glaucoma risk.

IOP is typically measured in the physician's office using Goldmann applanation tonometry, considered the gold standard method. But in-office tonometry provides only a single point snapshot of IOP; it cannot pick up common, and potentially harmful, daily pressure fluctuations, nor is intermittent testing an ideal way to monitor glaucoma treatment efficacy

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(or medication adherence). In fact, relying solely on occasional tonometry measurements may delay the detection and treatment of rising pressure that occurs between office visits. Thus, there is a need for a minimally invasive sensor technology capable of continuously measuring IOP in these patients—much like CGM is used to track blood sugar trends in people with diabetes.

There have been earlier attempts to measure IOP remotely using surgical implantables or surface sensors—for example, **AcuMEMS Inc.**'s *iSense* implantable sensor system and **Implandata GmbH**'s *Eyemate* implantable, both of which are placed during surgery; and **Sensimed AG**'s *Triggerfish*, a disposable contact lens that measures relative pressure and is placed in the eye for 24 hours.

Unlike these technologies, Injectsense's miniature, MEMS-based microsensor device (which measures about 4 mm X 1.2 mm X 0.5-mm thick) does not require invasive surgery, nor does it sit on the eyeball like a contact lens and potentially cause discomfort or placement difficulties. Instead, it is injected into the eye through a tiny 1.5-mm incision, and it sits in the vitreous space, self-anchored to the sclera, where it is undetectable by the patient. "This is the safest and most well-known entry point into the eye, and it leverages the intravitreal injection approach performed by the millions for wet AMD [age-related macular degeneration] patients," notes Cao. "The sensor is anchored on the sclera and sits away from the retina, away from the lens. You can rub your eye, you can push your eyeball, and it doesn't impact the sensor or any function of the eye."

Moreover, because the sensor itself is hermetically sealed and the device uses no polymers, "it can sit there for decades and there's no degradation of the electronics or accuracy," he adds.

The current version of the device is remotely powered externally, on demand, but a subsequent iteration will include energy storage so that the sensor can run continuously by itself, says Cao. The existing device also uses a wearable to extract the data, which is stored on the cloud, but the eventual plan is to minimize and complement the wearable using optical charging, he adds.

On the data analysis side, the company plans to let physicians set the pressure goalposts for their patients; Injectsense will provide the physician with clinically actionable information and alerts. Notes Cao, "We're not just about risk assessment; the primary use of our tool is for effectiveness monitoring. We will tell you if you achieve your target; but we are agnostic to whatever therapy you use, drug or device."

Injectsense hopes to complete the second phase of its animal studies later this year and begin first-in-human trials of the device for glaucoma in Q2 2021. It is pursuing an accelerated (*de novo* 510[k]) path to market and recently filed for FDA Breakthrough Device designation (a decision on the latter is expected by September).

Meanwhile, Injectsense is also working to expand its reach beyond glaucoma to other clinical areas that could benefit from the technology, of which Cao says there are many. The next likely application is in the brain. The company is currently in discussions with potential corporate partners that are interested in using the sensor technology to monitor intracranial pressure (ICP) in patients with hydrocephalus shunts. For that application, Cao notes, the sensor could be used to measure ICP independently or it could be integrated into the shunt valve itself to confirm the setting or detect shunt failure. Hydrocephalus shunts tend to fail every year or two, he points out, and it would be particularly helpful in pediatric shunt patients to know if their shunt is failing or if ICP fluctuations are due to standard ICP variability without having to subject them to tests in the hospital. Currently, neurosurgeons have limited visibility into long-term ICP wave forms, so they have no way of knowing whether fluctuations are due to shunt failure or normal variations. This device would provide further insight into how broad the fluctuations are, according to the company.

Cao also points to several other future potential uses for the technology. In ophthalmology, for example, an implantable sensor could be helpful for patients undergoing vitrectomy or cataract surgery—in this case, he notes, it's about having pre- and post-surgical data to see if something is going wrong. The sensor could also be injected into a muscle to monitor pressure in the tissues of patients with compartment syndrome, or it could be used in urology to measure bladder pressure. There are even possible applications deeper inside the body, he adds (which will require some engineering changes), such as measuring pressure inside a stented artery or detecting leaks from an implanted heart valve. There are numerous possibilities, and because the device is based on wafer-scale MEMS chip technology, it is "extremely inexpensive to produce in large volumes," Cao says.

Injectsense, which has three main patents on the technology, including coverage for injection of the sensor into the eye, completed a Series B funding round in April 2019 and has raised $14 million to date. It is currently in discussions on a C round with a series of strategic investors, and it has an undisclosed strategic partner/investor in the ophthalmic space.

The technology is particularly relevant right now, Cao points out, when the goal is to keep high-risk patients out of hospitals and clinics. "Now that we are doing social distancing, why do you need to bring the patient in to measure IOP?" he asks. "Just measure it remotely and use the cloud to see the results, trends, and alerts. And if you need to follow-up with a patient, that can be done using telemedicine." MTS

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