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Smart Orthopedic Implants' MOMENT

Since March, years of Darwinian-style stepwise medical evolution have collapsed into four months of disruptive change in medical practice because of the needs created by the global coronavirus pandemic. Remote patient monitoring is benefiting from the shift, with two barriers being removed in one fell swoop: reimbursement and the re-education of physicians. Start-ups Canary Medical and Intelligent Implants are seeing brighter prospects for their smart orthopedic implants.

- The widespread adoption of remote patient care necessitated by COVID-19 has given a boost to makers of implantable orthopedic sensors.
- These sensors, used with or incorporated into joint reconstruction implants, give surgeons objective patient data that could one day lead to specific, evidence-based indications for joint replacement.
- Other trends favoring adoption of these new data-gathering sensors include implant pricing pressure and the move to lower-cost care settings like ambulatory surgery centers, the incorporation of patient reported outcomes into FDA regulatory pathways and clinical trials, and the rise of risk-sharing agreements.

Companies operating in remote patient monitoring (RPM) have always faced two major challenges: one, reimbursement, or how otherwise to get paid for enabling superior medical care; and two, changing the practice of medicine, which evolves at a notoriously slow pace.

But because of the current pandemic, the CEO of a start-up developing a device with remote patient monitoring capabilities told *MedTech Strategist* that he was able to positively update his launch forecast. "We had allocated a certain amount of time for training doctors on the value of doing this, and all of a sudden, an entire generation has been trained in six weeks! Docs, patients, and payors all got trained on the first of March. Everyone is on the same page," he said.

The Centers for Medicare & Medicaid Services, which had already begun to recognize RPM as a valuable service with new CPT codes that went into effect in late 2019 aggressively loosened restrictions in mid-March so that more patients could be served during the COVID-19 emergency. (See *"New Rules and Regs Push Telehealth into the Mainstream,"* MedTech Strategist, *October 19, 2019* and *"COVID-19: A Pivotal Moment for Telemedicine and Remote Care Technologies,"* MedTech Strategist, *March 31, 2020*.)

According to a survey of 1,300 physicians conducted in April 2020 by Xtelligent Healthcare Media, prior to the pandemic, only 20% of physicians had adopted some form of telehealth. In early April, the survey found that number

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MARY STUART

to be 90% with 60% claiming that they would continue to practice it after the emergency. For once, the incentives for payors, providers, and patients are aligned, the latter group now having to consider the infection risk of going to a medical facility for a follow-up visit.

These pandemic-wrought changes bring the developers of smart orthopedic implants much closer to the realization of their market potential. These are sensors used with or incorporated into joint reconstruction implants to give surgeons objective information in situations where today they are forced to use their best guess.

Sensors and the relay of objective patient data into information platforms can immediately address two areas in orthopedic surgery that today are potential sources of variability and compromised outcomes: how the implant fits the patient (a goal for which **OrthoSensor Inc.**, for example, created its line of *Verasense* intraoperative sensors) and what the patient does after the surgery

In the future, the information from sensors could help the orthopedics specialty develop specific, evidence-based indications for total joint replacement and standardized metrics for follow-up, both still open to interpretation.

It's clear how these sensors could help improve care. With new sources of more accurate and reliable information from the patient, surgeons can track a patient's recovery after surgery and potentially intervene when problems are flagged to keep patients out of the hospital. Furthermore, in the process, surgeons will be building bodies of data from which to draw future conclusions about what works and what doesn't for particular kinds of patients, bringing evidence-based medicine to the orthopedic specialty.

Payment Models are Complicated Here

Start-ups and other innovators have proven that they can build the technology to do this job. However, reimbursement is complicated in this space, and the new remote patient monitoring reimbursement codes only assure that doctors get paid for using the information devices provide, although that does provide a mechanism whereby companies could charge a monthly fee for access to their data and still leave a profit margin for clinicians.

Device companies are still struggling with the models that recognize the value of their innovative devices. Bundling them in with the cost of the orthopedic implant itself isn't really feasible, with hospitals pushing implant prices ever lower. Noted one CEO of an orthopedic sensor company "It can be difficult to justify a $500 sensor when the hospital has already asked for a $500 reduction in the cost of the implant."

One company has already run up against the challenges of getting a new reimbursement code that rewards its innovation. **Consensus Orthopedics Inc**. was the first to seek a new code for its wearable device, the *TracPatch* (*see "Do Wearables Have a Medical Role in Orthopedics?"* MedTech Strategist, *October 31, 2018*).

The *TracPatch* remote monitoring wearable is applied before total knee arthroplasty (TKA) to establish a baseline for the patient and then for 90 days after the surgery, the standard recovery period. The device measures range of motion, activity levels, and temperature (an indicator of potential infection) and, paired by Bluetooth to a smartphone, also allows the patient to record pain levels and other key metrics.

Surgeons have access to a web dashboard and app that allow them to monitor a patient's recovery in real time. Although many surgeon users gave positive testimonials as to the value of *TracPatch* during the CMS hearing, the company's application for a new HCPCS code was turned down in November 2019, for several stated reasons, one being the fact that it's a wearable, not an implant, and another, an insufficient level of data quantifying its benefits. The company will appeal and, competitors have noted, will likely succeed in time, but it's an example of one of the challenges that developers face here.

And, while *TracPatch* is the most advanced product for post-total knee monitoring, its travails likely apply to a whole host of other such wearable orthopedic sensors in development at **Zimmer Biomet**, which is developing *Mymobility* in a collaboration with **Apple Inc.**, **Claris Healthcare Inc.**, **ActiGraph Corp.** (which was acquired in May 2020 by global private equity firm Archimed), the ear-worn e-AR sensor developed by Imperial College, London, and *activPAL3* from **PAL Technologies Ltd.**, among others.

Betting on Implants

A number of companies, including **Canary Medical Inc.**, in total knee replacement, and **Intelligent Implants Ltd.**, in spine surgery, both discussed below, are betting that embedding sensors in implants takes the burden of information gathering off of patients and increases the odds that they'll be used in ways that meet the requirements for reimbursement (i.e. continuous monitoring that's not disrupted by patient non-compliance). Intelligent Implants is further unique in also offering bone-healing electrical stimulation through its implant.

In addition to the tailwinds created by the pandemic, these companies are benefiting from other new payment models that could potentially recognize their value and help them command the pricing they seek. First, there are bundled payment models that embrace 90-day episodes of care, like the Comprehensive Care for Joint Replacement Model offered by CMS for Medicare patients. These reward providers for achieving better outcomes at a lower cost.

Other trends favoring adoption of these new data-gathering sensors include implant pricing pressure and the move to lower-cost care settings like ambulatory surgery centers (ASCs), the incorporation of patient reported outcomes into FDA regulatory pathways and clinical trials, and the rise of risk-sharing

agreements like that of mid-sized orthopedic firm **Medacta International** with the Gesinger Health System in Pennsylvania (see *"Skin in the Game: Risk-Sharing Models Develop for Medtech,"* Market Pathways, *May 29, 2020.*)

In short, the COVID-19 pandemic has given a push to telehealth, and that, coming on top of a number of other trends favoring orthopedic data gathering for evidence-based medicine, has created what appears to be a shining moment for orthopedic sensor companies.

Canary Medical: A "Talking" Knee Implant Offers Real-World Evidence

The success of total knee arthroplasty is, to a certain extent, in the hands of the surgeon. But almost equally important is what the patient does during the recovery period.

That period of time is somewhat of a black box for clinicians, who need to make decisions for patients based on their progress—recommendations that include courses of physiotherapy and the timing of the patient's return to work or other activities. In some cases, clinicians need to be alerted in a timely fashion so they can take action, for example, the physical manipulation of the knee before the scarring process results in movement-limiting strictures.

It's all the more important for clinicians to have objective, patient-specific information because physiotherapy and other post-operative care varies from one provider to another, and the availability and duration of physical therapy under the provisions of various insurance plans are also not consistent.

Finally, every patient is different. The post-TKA progress of a 70-year old with obesity is likely to be different from that of a 50-year old athlete. As more objective evidence becomes available, the field can advance with patient-specific treatment strategies; then it might be possible to predict, early on, which kinds of patients are likely to develop complications.

As noted, many digital health companies with wearable devices and apps for remote patient monitoring have been founded and funded to fill that information gap.

But wearables face a particular limitation, according to Bill Hunter, MD, CEO of Canary Medical (Vancouver, BC). "It isn't so much a technology problem as it is a human behavior problem." Patient non-compliance with medication schedules, keeping up diaries, lifestyle changes, or following any medical treatment plan, is a consistent problem across all of medicine.

As a former practicing physician, Hunter knew, for example, that if he prescribed antibiotics to a hundred patients, only a quarter would fully follow his recommendation. "Twenty-five percent of patients would never fill the prescription, 25% would take three tablets a day for 14 days as directed. The remaining 50% fall somewhere in between, with medicine cabinets filled with half empty antibiotic bottles."

Canary Medical believed patients needed something they didn't have to wear, charge, or interact with. "To design around human nature rather than technology, we needed something that would operate pretty autonomously."

—Bill Hunter, MD

In 2012, when Hunter, Chief Technical Officer Jeff Gross, PhD, and Fred Cushner, MD, an orthopedic surgeon at New York's Hospital for Special Surgery, founded Canary Medical, it was already clear that patients' participation in their post-operative recovery program is a key determinant of outcomes. The team therefore sought to remove lack of compliance from the equation by developing an autonomous implant.

Before beginning the development of a surgical solution, the team felt it was important to test out the efficacy of the wearable approach. At the Hospital for Special Surgery, about 100 patients were outfitted with high-end *Fitbits*. They were asked to wear the devices for a period before their surgery, and then again for 90 days after the surgery. "It's amazing how true to form the outcomes were," says Hunter. "Twenty-five percent never used it. There was a drop off from 75% at day one to 25% at 90 days. I suspect that if we had followed people for a year or two years, compliance rates would have dropped to close to zero."

Canary Medical believed patients needed something they didn't have to wear, charge, or interact with. "To design around human nature rather than technology, we needed something that would operate pretty autonomously."

That was the genesis of the *CHIRP* (short for Canary Health Implantable Reporting Processor), a remote patient monitor that requires little patient compliance or physician involvement,

because it reads out physiological data collected from within the surgically implanted knee joint.

The company's first product is well on its way to market, thanks to a partnership with a major (undisclosed) orthopedic manufacturer, under an agreement that provided development funding up front with additional payments as milestones are met, as well as substantial private funding. Insiders, friends, and family provided an $8 million seed round. That was followed by a $26 million Series A funding round led by GF Securities (Guangzhou, China) with the participation of BioScience Managers (Melbourne, Australia), Relentless Pursuit Partners (Vancouver, BC) and insiders.

Smooth sailing was further facilitated by the FDA: it granted Canary its Breakthrough Device Designation in October 2019, which will speed up development with timely FDA reviewer input and review.

A Founding Team at the Cutting Edge of Technology Convergence

Bill Hunter founded Angiotech Pharmaceuticals in 1992, which was instrumental in creating the brand-new category of drug-eluting stents. Jeff Gross was its CSO. Angiotech developed the paclitaxel coating for the *Taxus* coronary drug-eluting stent of Boston Scientific and the *Zilver PTX* paclitaxel-eluting peripheral stent of Cook Medical.

Now, Canary Medical is incorporating electronics for remote patient monitoring into knee implants, a problem that is "very different and yet not so different," says Hunter. "The premise behind Angiotech was pretty straightforward. Medical devices get infected and inflamed, and pharmaceutical companies make these cool things called anti-infective and anti-inflammatory medications, so why not put them together?"

With experience in stents, he believes the next coronary convergence opportunities lie in incorporating sensors and remote patient monitoring technologies into stents, heart valves or other vascular implants to provide an early warning system of failure, future potential applications for Canary.

But Canary's first application is in orthopedics, in particular, total knee replacement, for a variety of medical and technical reasons, Hunter says. First, it's a large market (800,000 TKA procedures annually in the US) after which, as noted, there is a need to monitor the patient. The monitoring opportunity is particularly attractive in the knee, because there, post-surgical satisfaction rates are much lower than they are for hips.

From the technical standpoint, orthopedic implants are physically large enough to incorporate a first generation of sensor arrays powered by small pacemaker batteries. "Pacemaker batteries are now so good that one battery can power the implant and monitor the patient for 20 years, which is basically the lifespan of a hip or knee." Nothing needs to be charged, or replaced, Hunter says.

Measuring What Matters in the Knee

Canary Medical's sensor array technology is borrowed from the drone industry. "Sensors grounded by gravity allow a drone to know precisely where it is in three-dimensional space." Measures of joint functionality are also dependent upon three-dimensional measures.

Within the *CHIRP* are 3D gyroscopes, 3D accelerometers, and a step counter, and these allow for the measurement and reporting of patient activity levels, range of motion, and a patient's particular gait. First-generation *CHIRP* is contained in the "dead space" of an orthopedic implant's tibial extension; future, smaller versions could be incorporated into the tibial plate, according to Hunter. Both physicians and patients will have access to the information—physicians on a dashboard that gives them metrics relative to patient management and complications, patients on an app that gives them information useful to rehabilitation and recovery.

Hunter points out that many wearables have step counters, and that's good information but not sufficient in and of itself because not all steps are the same. "When doctors do post-op follow-up in their office, they ask their patient to walk down the hallway. They want to see if the patient is balanced, limping, exhibiting a short, painful stride, or taking a long athletic stride."

With data on activity levels, range of motion, and gait parameters, Canary could help make it easier for doctors to assess patients today and in the future, because *CHIRP* creates a digital record against which to quantify future patient progress. While orthopedic clinicians are experts at assessing a patient's condition by observing their gait, it's difficult to remember precisely how they walked in the previous visit. CHIRP will make it possible to quantify even small improvements or regressions.

With this information, clinicians are able to manage by exception, looking at their daily slate and picking out the patients who are not progressing as well as they should be, or who seem to be having trouble. "Imagine a scenario where the doctor can say 'Mr. Jones, your activity levels are low, your range of motion seems pretty limited, and your gait is suggestive of someone in pain. Why don't you come in to the office?' You want to proactively implement medical and physiotherapy changes to keep that patient out of the emergency room," Hunter says.

At the same time, clinicians could reduce the costs of unnecessary home or office visits after remotely reading the data, letting the

patient know, "Mrs. Smith, your range of motion is good and your activity level is high, so if you aren't experiencing any problems, I don't need to see you for another six weeks."

Monetizing a Remote Patient Monitoring Platform

Under new CMS remote patient monitoring CPT codes physicians are reimbursed $115 per patient per month for reading and responding to the data, as long as it meets certain criteria (the data must be physiologic, relevant to the condition being treated, and captured for at least 16 days out of a 30-day period.) "This could be an extra $1,000 per patient per year for remotely monitoring patients. If you are a busy surgeon who does 300-400 surgeries a year, that's meaningful compensation for closely following your patients after surgery," notes Hunter.

The smart implant itself could possibly be directly reimbursed under an NTAP (new technology add-on payment) code for Medicare patients, which account for 55-60% of TKA patients, although these are extremely difficult to obtain, requiring companies to demonstrate that they offer a significant improvement over the standard of care. Or, as noted earlier, it could be priced according to the value it brings to bundled payment models like Medicare's Comprehensive Care for Joint Replacement (CJR), which pays a fixed amount to the hospital performing the knee replacement.

The CJR bundle, for example, pays $25,000 per patient to the hospital for performing a knee replacement and providing 90 days of follow-up care. Within the $25,000 total there is an allocated cost for each aspect of care (*see Figure 1*). If the hospital can deliver care for less than $25,000, say by reducing readmissions, then the patient is profitable for them. Conversely, if the patient costs more than $25,000, due to extended hospitalization, for example, then the hospital loses money on that patient. Many private insurers use the same system, often offering a larger ($35,000-$40,000) bundled payment.

Addressing Sources of Dissatisfaction and Failure

Canary Medical aims to give doctors the opportunity to remotely monitor patients and potentially intervene during the patient's course of healing, according to the same measures they use when they use their clinical skills to assess their patient in the office.

But it turns out that the platform is also capable of providing unique medical information that is not available by any means today. Hunter describes the sensor array as functioning like a tuning fork that "pings" different frequencies depending on how firmly it is incorporated into the surrounding bone. "Every time your heel hits the ground, the tuning fork pings," and those vibrations can be measured and, eventually through machine learning, correlated with both normal and abnormal outcomes.

For example, when the implant first goes into the knee, it hasn't yet healed and is more loosely held in place, which would create a certain pinging pattern. As normal healing progresses and the prosthesis anchors in place, the fit gets tighter, dampening the vibration pattern. "We will be able to see the progression of bony incorporation, or the natural progress of healing, because we will pick up a change in frequency as the tibial stem secures in place." Conversely, loosening or infection could be detected by sensing an absence of expected vibration dampening.

At the same time, the device might identify sources of patient discomfort. Approximately 20% of TKA patients are dissatisfied with their new knee, and this is often attributed to micromotion, or a laxity of the artificial joint causing a feeling of instability. "With our device not only can you detect micromotion, but you can also "see" where it is coming from. Is it anterior/posterior, medial/lateral? Is it one cm or five mm? We can locate it and quantify it, which might make it possible to correct it."

Fifteen years after surgery, it is theoretically possible that the sensor could pick up vibration signatures indicative of impending implant failure, so clinicians could intervene before significant surrounding bone loss occurs.

This a future vision for Canary Medical, which, with essentially the same technology, next plans to expand its platform to hip and shoulder joints. After that, it is slating trauma indications and spine. "Orthopedics is gen-one, vascular is gen-two, and there we will probably start with AAA grafts and the detection of endoleaks. Being able to detect pressure changes in the aneurysm sac will be a gamechanger," says Hunter.

Within the next few months, *CHIRP* for TKA will go in front of regulators. When approved, the product will be sold with Canary's orthopedic partner's flagship knee products. "With expedited review, it should be approved in early 2021, says Hunter. "With a little luck the 'talking knee' will walk out of an operating room in less than a year!"

Intelligent Implants: Solving the Biggest Problem in Spine Surgery

In its implantable device, Intelligent Implants combines both therapy and remote patient monitoring to help boost rates of spinal fusion, reduce revision surgeries and hospital visits, avoid follow-up x-rays, and return patients to active living sooner. And it aims to do so without relying on controversial bone growth factors that, for lack of a better alternative, are in widespread use.

Spinal fusion surgeries, which are done more than 1.6 million times in the US each year, are the most expensive surgeries performed in hospital operating rooms. They're several-hour-long procedures that require teams of orthopedic surgeons, neurosurgeons, and other staff, and can run upwards of $100,000 per surgery. Yet for that high cost, failure rates are high—from 20-40%, depending upon the type of procedure and the type of patient. (Failure is generally defined as non-union, that is, bone growth doesn't succeed in uniting the affected sections of the vertebrae as the patient heals.)

In addition, one-fifth of spine surgery patients are readmitted to the hospital within 30 days of the procedure. Most of those readmissions are unplanned and result in billions of dollars in healthcare costs each year (according to a 2017 article in the journal *Spine,* by Adoga, O., and Elsamadicy, A. *et al*).

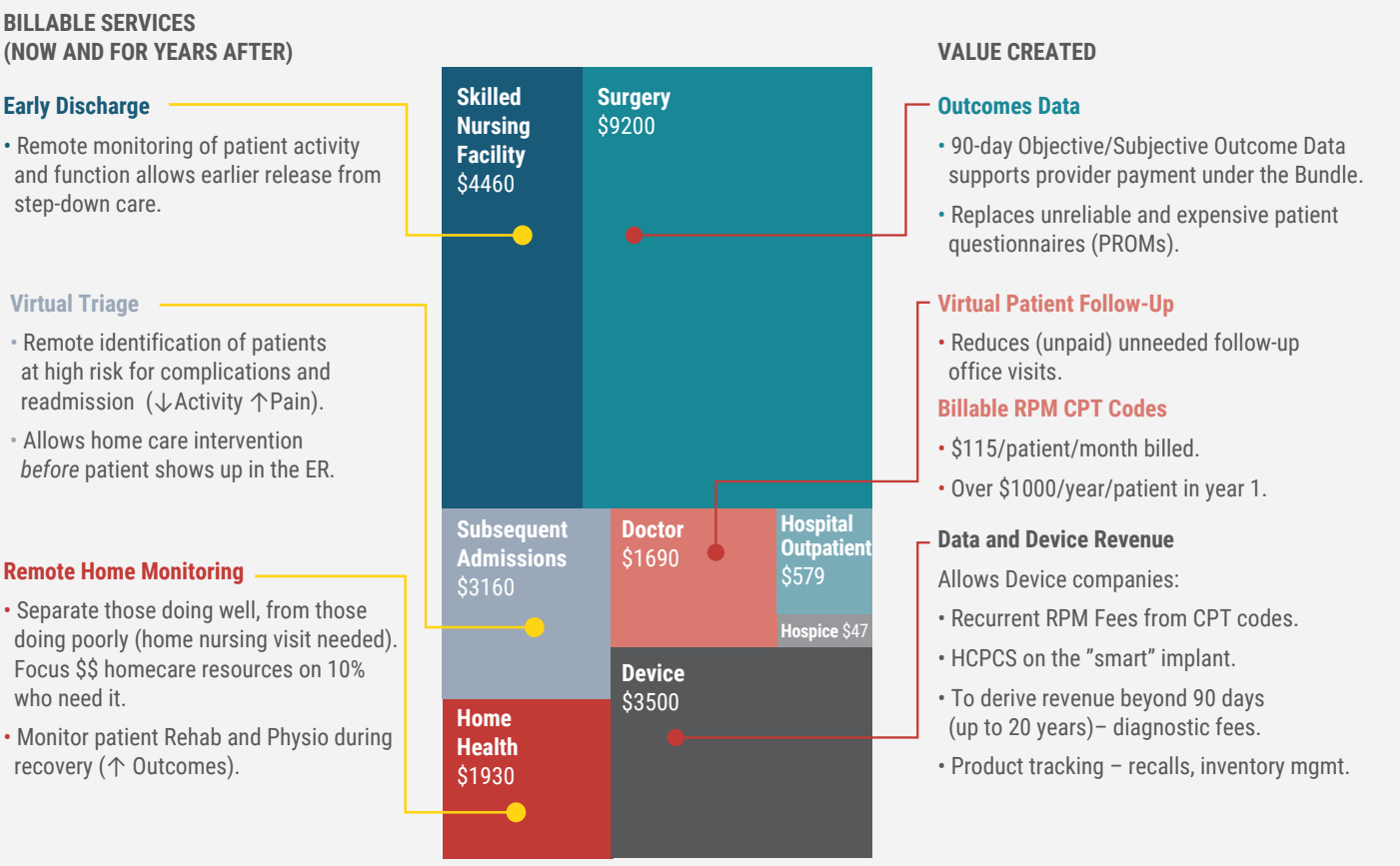
The human cost is significant as well. Two brothers and co-founders of Intelligent Implants (Mölndal, Sweden, Cork, Ireland, and Houston, TX), have a close relative who suffered greatly through many spine surgeries. Prior to her first fusion surgery, she was unable to walk due to excruciating pain. Her back surgery failed, and she underwent a subsequent revision procedure incorporating a bone growth factor to encourage fusion. Fusion occurred all right, but she developed a new source of pain requiring a third procedure. At that point, the surgical team had to file down bony overgrowths (heterotopic ossification) on her spinal nerves, one of the potential side effects of the bone growth factor rhBMP-2. "She has never gotten well," says Erik Zellmer, PhD, Chief Technical Officer of Intelligent Implants.

Technologies Converge to Create a New Solution

This experience was no doubt a deciding factor in the founding

Figure 1

Smart TKA in the "Bundled" CJR Environment–Reducing Costs and Measuring Outcomes*



*Dollars represent, out of a total of $25,000 paid per patient to the hospital for a TKR under the CJR bundle (including 90-days of follow-up care), the allocation of costs to each aspect of care. For example, the surgery slice of $9,200 includes $3,500 for the total knee implant, $1,690 to the surgeon, $3,160 for patients being readmitted for complications, etc.

Source: Adapted from "Medical Supplies & Devices: CJR is Here," Raj Denhoy (Jefferies Equity Research, 2016)

of Intelligent Implants in 2014, which first came about after Erik Zellmer was finishing his PhD in biomedical engineering at Washington University (St. Louis). There he became friends with Rory Murphy, MD, a neurosurgeon who was finishing up a rotation at the WashU medical school.

Observing some spinal fusion surgeries, the two learned about the problem of non-unions. Zellmer, who was familiar with the potential for neuromodulation to encourage healing, and Murphy, who knew about instrumented spine surgery, thought to start a company that would embed an electrical neurostimulation device into a spine implant. As co-founders of Intelligent Implants, they brought in experienced business manager [and Erik's brother] John Zellmer, CEO, and life science investor Martin Larsson, one of the company's first investors, to head up fundraising.

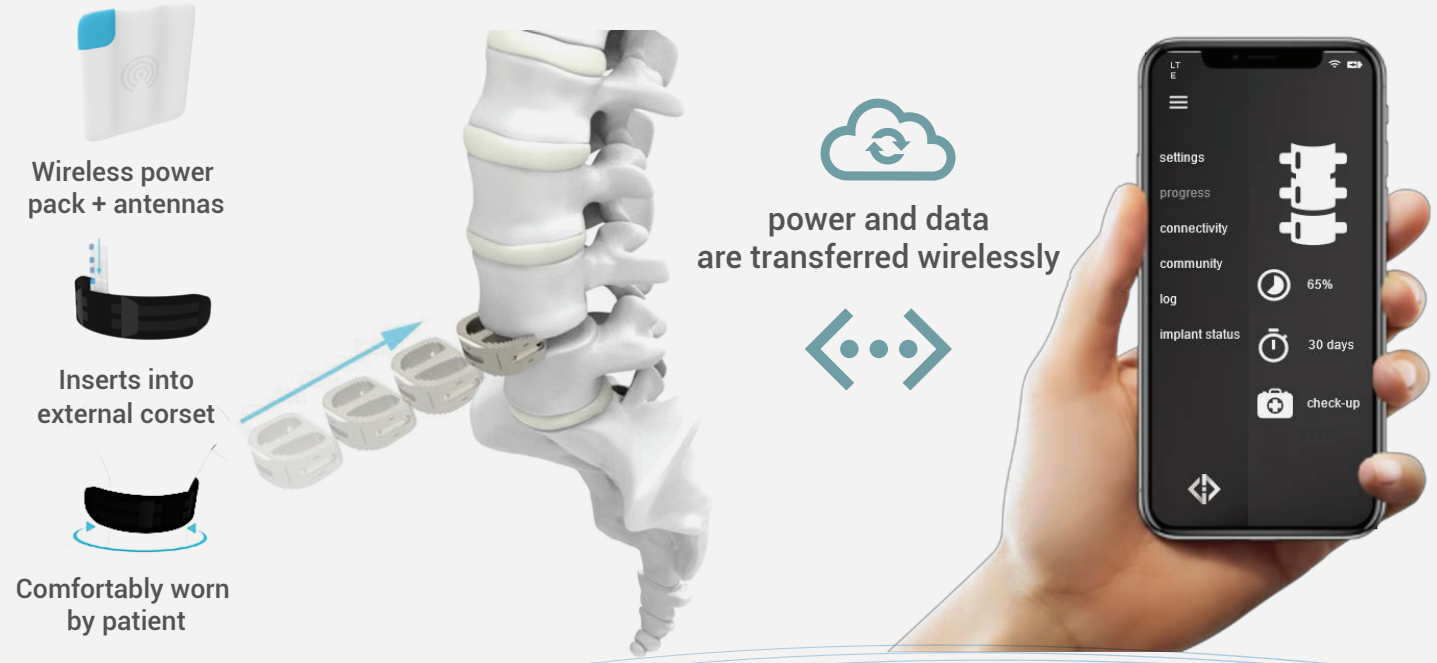
At the pre-seed stage, the company has raised just over $3 million, from SOSV, the venture capital firm that supports the incubator Hax (Shenzhen, China) into which Intelligent Implants was invited; the TMC Venture Fund (of the Texas Medical Center, one of Intelligent Implants' locations); AngelMD, which syndicates angel investor who are physicians; Enterprise Ireland; Bioverge; private Swedish investors, and the founders. (For more on Bioverge, see *"Bioverge Fills a Gap in Early Stage Investing,"* MedTech Strategist, *February 5, 2020*. For more on the incubator at the Texas Medical Center, see *"The Magic of Innovation: An Interview with Billy Cohn, MD,"* MedTech Strategist, *October 21, 2018*).

Three in One: Therapy, Monitoring, and a Data Bank

The founders knew that to gain widespread adoption of their new device, they must not change the workflow of surgeons. The start-up's first product, *SmartFuse*, was therefore designed to fit inside the most commonly used implant for spinal fusion, the intervertebral fusion cage, used in more than 350,000 surgeries in the US each year. These it manufactures at the **Johnson & Johnson** Center for Device Innovation in Houston, as the first external company invited into the facility.

SmartFuse, accomplishes three things: one, it uses electrical stimulation to speed up the natural process of bone growth; two, it shapes or sculpts bone growth through an eight electrode array through which energy delivery can be adjusted; and three, it monitors bone growth and informs clinicians of the progress so they can determine when mature bone has permanently united the adjacent spine segments (see *Figure 2*).

Figure 2
***SmartFuse* Implant Provides Both Therapy and Monitoring**



Source: Intelligent Implants

> "We are stimulating the bone to grow naturally without using any biologics. We are amplifying the natural signal to decrease the risk of failed surgeries. We cut the healing time in half so patients can get back to work or an active lifestyle earlier."
>
> —John Zellmer

The PEEK implant has a standard cage shape and has integrated electronics, electrodes, sensors and antennas. It is powered wirelessly, by induction, from a power pack and antennas inside a standard garment worn routinely after spine surgery; a cervical collar or corset (wrap-around support garments). Data thus collected is uploaded to the cloud by the external power pack, which is in constant two-way communication with the implant. There it is processed and sent to a surgeon interface on a smartphone.

SmartFuse, which operates on a low level of DC current, can direct bone growth or bone reduction in specific areas through its array of eight electrode, each being able to deliver a negative (bone inducing) charge, or a positive charge (that decreases bone). A bone dissolving effect might be necessary in cases where you want to avoid bone growth close to nerves and other soft tissues. Individual electrodes can also be turned off, or the stimulation mode can be entirely turned off, if the patient gets back on his or her feet very early. Or, in the case of a fusion failure, it could be turned on again.

SmartFuse can monitor bone growth in real-time, allowing surgeons to confirm when patients have healed completely. The implant uses impedance tomography to measure the resistance of current as it passes between electrodes, an indicator of how much bone has grown and the level of its maturity. Erik Zellmer notes that impedance tomography is how electrodes are checked in cochlear implants, to make sure they're working, and that impedance tomography can do the same thing here, although "We don't expect our electrodes to break," he says. The main purpose, as noted, is to determine the rate and quality of healing.

In large animal studies, the company has iterated the platform to the point where it now understands which energy delivery dosage achieves the best therapeutic effect. In sham controlled large animal studies, the company has seen data at six weeks that suggests dramatically more rapid bone formation, "at six weeks about 2.75 times more bone compared to autograft, the gold standard for fusion," John Zellmer says.

In the near term, the company is conducting GLP preclinical studies. Notes Erik Zellmer, "In the last couple of years we have shown that it works, and at what dosage it works really well, so now we are going into full regulatory mode." The company will conduct its first clinical trial soon, and anticipates having its first pre-submission meeting with the FDA in a couple of months.

The first application of *SmartFuse* will not be diagnostic, but rather data-gathering. John Zellmer notes that as the company builds up a large body of data, it will be able to use machine learning to become diagnostic and to personalize stimulation for individual patients. Patients will likely be on the system for 12 to 20 weeks following surgery, or less, if precise information from use of the device indicates speedy healing.

After the initial product launch, Intelligent Implants plans to work on incorporating therapy and monitoring into hip implants and long bone nails.

John Zellmer sums up the company's value proposition. With fusion rates potentially as good or better than those of bone morphogenetic proteins (and, although early data is promising, that remains to be proven), *SmartFuse* could avoid the high cost of those biologics ($2,500-$5,000 for each package of rhBMP-2) as well as their potential adverse effects, which, beyond heterotopic ossification also include radiculitis, pseudoarthrosis, and seroma/hematoma formation. "We are stimulating the bone to grow naturally without using any biologics. We are amplifying the natural signal to decrease the risk of failed surgeries. We cut the healing time in half so patients can get back to work or an active lifestyle earlier," he says.

Because *SmartFuse* also monitors bone growth, the company can cut down on the cost of x-rays and CT scans, avoiding exposing the patient to radiation, and, which is really key these days, help patients avoid trips to healthcare facilities.

"We can reduce the risk of a non-fusion occurring by more than 75%. This could be revolutionary in the orthopedic spine market," says John Zellmer. MTS

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