

## Device Offers Pain Relief From Chronic Bladder Infections

Massachusetts Institute of Technology



When Massachusetts Institute of Technology (MIT) professor Michael J. Cima, Ph.D., learned that the most commonly used treatment to relieve the pain of interstitial cystitis (IC) is ineffective and can cause severe complications, he thought, “I can do something about that.”

One aspect of MIT’s mission is to commercialize technology arising from the research conducted by its inventors. Cima fulfilled the mission by inventing a device to treat the pain of hundreds of thousands of people in the United States who suffer from IC, a chronic inflammation of the tissues of the bladder wall that causes patients to make as many as 50 trips to the bathroom every day. Cima, who teaches material science and engineering and is the inventor of several medical devices that incorporate material science technology, assembled a research team in 2007 that includes peers from MIT and one from Children’s Hospital Boston. By the end of one year, the team came up with a drug-delivery system called LiRIS, which stands for lidocaine-releasing intravesical system.

Now in its first phase of clinical trials, LiRIS is “moving along rapidly and is expected to reach the market within five years,” says Tom Tachovsky, Ph.D., a technology licensing officer at MIT. The device, licensed by the MIT Technology Licensing Office and its licensing partner, Children’s Hospital Boston, is being tested and will be manufactured and

marketed by Taris Biomedical of Lexington, Mass., which was founded in 2008 by Cima and others specifically to launch LiRIS.

“Big companies are not always willing to invest in new technologies such as this,” says Tachovsky. “So we felt licensing to a startup, which is more willing to take some risks, would be the best way to develop this device.”

Plus, says Tachovsky, this approach benefited from another important asset: the innovator himself. “Michael is not only an academic, but he’s a serial entrepreneur so we were confident that, with him providing scientific guidance, the technology would be commercially developed.”

### How LiRIS Works

“*The current treatment for alleviating the pain of IC consists of infusing a “wash” of dimethylsulfoxide and lidocaine into the ureter through a catheter. Relief lasts about 90 minutes, at most. Patients often call their urologists an hour later in dire pain.*

LiRIS, however, delivers an extended-release dose of lidocaine, which lasts about two weeks, directly into the bladder through a tube designed by Cima that is made of elastomers, which are a type of polymer. Both the current treatment and the one using LiRIS are performed in a doctor’s office.

Cima says LiRIS uses shape memory technology that allows it to “fold up into the shape of a pretzel so it stays inside the urethra” — the canal that empties from the body the urine that collects in the bladder.

LiRIS is less invasive, greatly reduces the chance of infection and can be easily inserted and removed. Also unlike the current system, the device isn’t at risk of damaging the bladder or causing possible side effects.

### The Heartbreak of IC

According to the National Kidney and Urologic Disease Information Clearinghouse, more than 1 million people in the United States suffer from IC, a disease of unknown origin. IC is sometimes called overactive bladder, a term that belies its severity, says Cima. In addition to constant pain, sufferers experience incontinence, urinary urgency, debilitation, depression and the reality that there is no cure.

In addition to the current treatment of douching the bladder through a catheter, other treatments — such as oral opioids, relaxation techniques, physical therapy and biofeedback — are used but with, at most, temporary success. When all else fails, doctors sometimes remove the bladder.

“But even then, patients still have pain from the nerve damage caused by the repeated wash treatment,” Cima says.

To add insult to injury, as recently as 15 years ago “urologists thought patients who had all the symptoms of IC were crazy,” he says. “They did not think that IC was a real disease.”

But for those dealing with chronic pain and the decrease in quality of life that came with it, IC is very real. Cima says some of the clinical study patients have tracked him down at his office because they’re so desperate to get relief from the constant pain.

Only about half of IC sufferers have been diagnosed with the disease, Cima says, because the remaining half are too embarrassed to talk about their symptoms with their doctor.

Patients usually display symptoms for a long time prior to diagnosis. IC usually is diagnosed by ruling out other

possible conditions. It is common for doctors to misdiagnose the disease as a bladder or urinary tract infection, and then to prescribe antibiotics, which do nothing to help. On average, it takes about 18 months to diagnosis IC, Cima says.

## **Relief Is on the Way**

LiRIS comes not a moment too soon, and no doubt it will be enthusiastically received, Cima says, not only by those who suffer from IC — predominantly women and older men — but also by urologists, because “there’s a huge unmet need.”

The beauty of the LiRIS device is that “it’s not rocket science,” says Cima, whose team is composed of MIT researchers Mario Castillo-Ortiz, Karen Danielle Daniel, Steven Froelich, Hong Linh Ho Duc, Grace Young Kim and Heejin Lee, as well as Jordan Dimitrakov of Children’s Hospital Boston.

“Our objective is to keep the cost of care less than or equal to what it is now,” Cima says, “and to produce a more efficacious outcome. LiRIS is designed for flareups and episodic pain, which means that patients need to be treated three times a year. That means three office visits to put the device in and three visits to take it out.”

## **The Benefits of Cross-Disciplinary Collaboration**

LiRIS, Tachovsky says, is good example of collaboration among disciplines at MIT.

“Usually there’s little cross-talk between disciplines,” Tachovsky says. But that isn’t the case with Cima, whom Tachovsky calls representative of a “new era of investigator” who uses his expertise in material science and engineering to tackle medical problems and “come up with integrated solutions.” Cima does his research at the Koch Center at MIT, a facility designed to mix faculty, postdocs and students on each floor thus promoting interdisciplinary collaboration.

In the case of LiRIS, Cima and his team collaborated with MIT’s departments of biology and mechanical and electrical engineering, as well as with researchers at MIT’s David H. Koch Institute for Integrative Cancer Research. The various departments shared the expense of bringing LiRIS to fruition and also were funded by MIT’s Deshpande Fund, which was created in 2002 to help technologies and ideas developed in the institute’s labs make their way to the marketplace.

## **Next Steps**

At Taris, LiRIS is nearing the end of Phase 1, which is the developmental stage in which Taris’ scientists continue to work on LiRIS’ design, do human testing and collect data. The Food and Drug Administration then will review Taris’ protocols and determine if the company can move to Phase 2.

Upon FDA approval of the final version of LiRIS, which Tachovsky estimates could happen as soon as 2014 or 2015, LiRIS will be put to use in the offices of urologists in the United States and, Taris hopes, doctors’ offices throughout the world.

Last year, volunteers in Taris’ clinical study tested the LiRIS device without the lidocaine to see if they could feel it in their body. No one could sense it, Cima says.

“What we learned with an empty system is that the device is highly tolerable,” says Julie Himes, M.D., who is one of Taris’ founders, its chief medical officer and its senior vice president of clinical development, as well as an internist in infectious diseases.

Not only is the device comfortable for users, Cima says, it’s also not harmful.

“We’re very confident that what we’re doing is safe,” Cima says.” Our data are clear on this. Now we’re building a case by conducting carefully controlled studies that show that LiRIS is efficacious.”

In addition to helping alleviate the pain of interstitial cystitis, Cima and his team believe that LiRIS eventually can be used to deliver chemotherapy to patients who have bladder cancer and to aid in the treatment of other diseases of the bladder. He says there’s also the possibility that LiRIS can be designed to provide pain relief for longer than two weeks.

“Urologists whom we work with in our clinical trials are very excited about LiRIS,” Himes says. “They’ve given us lots of feedback — all helpful and positive.” One of the nicest things about LiRIS, Himes says, is that Cima and his team have invented a technology that “fits well with what urologists currently use in trying to treat interstitial cystitis.”

This means that “doctors will find LiRIS easy to deploy,” she says, and that it will be adopted rapidly.

More importantly, says Tachovsky, this technology has the power to help millions of people recover from chronic pain and make huge gains in quality of life. “This device is offering hope to lots of people,” he says. “I feel fortunate to be part of that.”

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