

Implantable pain disk may help those with cancer

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An estimated 3.5 million cancer patients around the globe are in severe pain from their disease, but many get no relief.

In poor countries the cost is considered too high for drugs like morphine when such opioids are often stolen, abused or not taken according to instruction.

But some Johns Hopkins University scientists have been working on a solution for those patients, as well as some in the United States, that uses a flexible button-sized disk implanted under the skin that releases consistent doses of painkiller over a month. No pills, no measuring, no trips to the clinic.

If an upcoming clinical trial for safety goes well, the device could be available next year, doctors say. It also could be retooled to treat other diseases and injury, and maybe even some opioid addicts.

"With all the problems, the health officials (in developing countries) would prefer to spend money on antibiotics that cure diseases, vaccines that prevent diseases or children with a long life ahead of them rather than those with terminal cancer," said Dr. Stuart A. Grossman, a Johns Hopkins professor of oncology, medicine and neurosurgery and a [pain](#) management expert in Hopkins' Sidney Kimmel Comprehensive Cancer Center.

Grossman grew up overseas but when he returned to India and other

[poor countries](#) as an [oncologist](#) and worked in cancer centers he saw how hard it was for patients with cancer to get opioid [pain medications](#). He and others began working on a solution about 15 years ago. They came up with something that works a little like Norplant, the rods inserted under the skin that release contraceptives over weeks.

Only this round, plastic disk just over a centimeter wide delivers hydromorphone, a more potent form of morphine, through a channel in its center. The rest of the device is sealed to prevent an initial burst of the drug that could kill a patient.

The disk could be made wider to deliver drugs longer, or thicker to deliver higher doses. It eventually could deliver a different drug or be used by veterinarians on animals. But for now, the scientists are focusing on one device for [cancer patients](#) that would cost about \$50 a month, or about the same as the bill for relatively cheap morphine pills.

With Hopkins' blessing, Grossman patented the device and formed a company called Axxia. Dr. Suzanne A. Nesbit, a clinical pharmacy specialist in pain management and a research associate in the Hopkins oncology department, will run the clinical trial, which was delayed a bit when the maker of the plastic they preferred decided to stick to producing the soles of shoes.

They're working with a new plastic that already is approved for medical implants by the U.S. Food and Drug Administration but requires some fine tuning.

The clinical trial for the disk will be conducted in the Philippines, Singapore and East Baltimore, where Hopkins has a presence.

Grossman said a U.S. manufacturer would make the drug device and Axxia will rely on pharmaceutical companies around the world to

distribute it and train doctors unaccustomed to assessing pain, dosing and monitoring patients.

Some of those who treat pain and addiction believe the disk would serve some populations well and look forward to having another tool for tricky patients, though they also see some challenges.

There are an estimated five million Americans on opioid therapy for pain, or 2.5 percent of the population, though most take a short-acting, low-dose Vicodin or similar pill and not every day, said Dr. Nathaniel Katz, the director of the nonprofit Program on Opioid Risk Management at the Tufts Health Care Institute.

Opioids don't work well managing everyone's pain, and about 5 percent of people who take them become addicted to the medications. Others don't stick to their regimen, said Katz, who is also the CEO of a pain-drug development company called Analgesic Solutions.

There may be a role for Grossman's pain disk in addicts and those who don't follow their prescriptions, he said.

"There are people out there who would benefit from having something in their body releasing drugs at all times that doesn't involve the patient and can't be changed by them," he said. "These are people who you fear might overdose if you give them pills, or there is an abuser in the household, or the person has mental illness like PTSD, or Parkinson's disease."

Many don't have consistent pain, and it would be better if they could change their dosage as needed, Katz said. But when that's not possible, some relief is better than none, Katz added.

The disk, he said, may not solve all illicit use of the drug. Even though

they are meant to be implanted by a doctor, addicts are crafty and will find ways to acquire them, melt them down and ingest them, said Katz, adding many such recipes end up on Internet.

Some addicts have been known to eat pain patches even though that can be fatal, Katz said.

The disks could only be used to treat addiction if they delivered a different drug than hydromorphone because that drug is not approved by the FDA for treating addiction, only for pain, he said. Only methadone and buprenorphine currently have that stamp from the FDA.

There is a growing need for new treatments for addiction to prescription drugs such as oxycodone and morphine, said Dr. Michael Fingerhood, an associate professor of medicine at the Johns Hopkins University.

The number of admissions to Maryland Alcohol and Drug Abuse Administration-funded treatment programs for prescription drug addiction doubled to 7,000 between 2007 and 2010, according to the state Department of Health and Mental Hygiene.

Others, especially teens, find unused opioids in their parents' medicine cabinets. About 2,500 American teens use prescription drugs every day to get high for the first time, according to the Partnership for a Drug Free America.

Maryland joined dozens of other states this year in creating a database to track filled prescriptions so doctors know when someone may be shopping for extra drugs, but the system is not yet up and running.

The trend is likely to continue until doctors stop prescribing so many addictive drugs, said Fingerhood, who treats addicts.

He said addicts still often have pain, but the pain becomes difficult to treat because they can't be handed more pills. This is where Dr. Grossman's disk may come in.

Not for treating the addiction -- there already is a similar rod implant developed by Titan Pharmaceuticals Inc. awaiting FDA approval that contains buprenorphine for that purpose. But to treat the pain, said Fingerhood, who also is the director of the division of chemical dependence at Hopkins Bayview Medical Center.

"It's a great option for pain," he said. "It's treated poorly now in this population because they can't take traditional pills. ... And I think implants are going to be the wave of the future with other medications as well."

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