

Treatment for painful curved penis shows promise

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Xiaflex up for FDA approval later this year, but some experts think injections required would be a tough sell.

(HealthDay)—Some diseases are especially tough to discuss. When Tony Lee realized that his penis was curving whenever he had an erection—making it painful and difficult for him to have sex—he had no idea what was wrong. He became depressed and very worried, and his relationship with his wife started to change.

"For a man to dread sex, it's just not natural," he said. "There were times when I would stay up late on purpose, just to make sure my wife was sleeping before I got into bed. I was just totally embarrassed."

His wife finally convinced him to see his primary care physician, who referred him to a [urologist](#). The specialist told him he had Peyronie's disease, a [connective tissue disorder](#) involving the growth of fibrous collagen plaques in the soft tissue of the [penis](#). The condition can cause

pain, erectile dysfunction and shortening of the penis.

The diagnosis was difficult to face.

"You do freak out. It's such a personal area. It's like, 'Noooooo! Why couldn't I just lose a finger? Anything but this,'" said Lee, who is 46. Lee asked that his full name not be used.

Experts estimate Peyronie's disease, a [connective tissue](#) disorder, affects at least 5 percent of men. Although the cause of the disorder is not known, physicians think [genetic predisposition](#) and repetitive minor trauma to the penis during [sexual activity](#) may play a role. People with diabetes, and those who have had [prostate cancer surgery](#) or erectile dysfunction, are also susceptible to the disease, according to Dr. Larry Lipshultz, a professor of urology at Baylor College of Medicine.

The treatment options are very limited, and there is no cure. "There is no oral or topical medication," said Dr. Elizabeth Kavalier, a urologist at Lenox Hill Hospital, in New York City. "You can excise the plaque and tighten up the other side, but that reduces the length, or you can use a penile prosthesis."

Lipshultz said he's had some luck with about half of his patients when he gives them a drug called verapamil, a calcium channel blocker, which is injected into the shaft of the penis. The use of the drug is based on its ability to degrade collagen, slowing, preventing or even reversing plaque formation and the progression of Peyronie's disease, according to a 2002 study published in the *International Journal of Impotence Research*. A verapamil gel that is applied to the skin is also sometimes used, according to Kavalier.

Lee, who has been dealing with Peyronie's for about two years, has used a "straightening machine" that stretches the penis, and he participated in

one of two [clinical trials](#) for a new drug that is up for review by the U.S. Food and Drug Administration: Xiaflex, produced by Auxilium Pharmaceuticals Inc. He said his penis is now 70 percent of its pre-disease length as a result of the interventions.

Xiaflex, which breaks down the scar tissue that is a component of penile plaque, was approved by the FDA in 2010 to treat Dupuytren's contracture, an inherited connective tissue disorder that causes the fingers to bend toward the palm. The concept of using Xiaflex with Peyronie's is based on some common features of both diseases. The hand condition is caused by an abnormal buildup of a substance called collagen. Fingers begin to bend toward the palm and the patient cannot straighten them.

The two clinical trials designed to test how Xiaflex worked in people with Peyronie's disease—done in 2011 and 2012—together involved a total of 551 patients who received Xiaflex and 281 who were given a placebo. Each participant received four to six injections with a small needle into the penis every 25 to 72 hours over a period of several weeks. "The results showed people got a 30 percent improvement in curvature, which is clinically significant in terms of function," Lipshultz said

Recent data on the treatment appeared online in February and will be published in the July print issue of the *Journal of Urology*.

Lipshultz, who was involved in the clinical trials and is paid by Auxilium to speak to physicians about the treatment, said the company thinks Xiaflex will be approved by the FDA by mid-September.

Yet, Kavalier expressed concerns about whether Xiaflex will be helpful.

"The data show it looks like the drug made people feel better about their

condition, maybe because they were getting treatment in the clinical trial, but I'm not sure if functionally it made a big difference," she said. "I don't think I could convince somebody to let me inject their penis four to six times with the hope of getting some small improvement."

Side effects from the injection of the drug included: bruising, swelling and pain. There were also three serious adverse events involving penile fracture and three hematomas, according to Auxilium Pharmaceuticals.

But Lee is hopeful.

"I was so far gone with this, the curvature was so bad, and so I feel a whole lot better about myself now," he said. "It's kind of like if a person was paralyzed, and then all of a sudden you can walk, even though you might need assistance, it's a wonderful thing. That's how I'm looking at it."

Lee encouraged people to involve their partners to help them deal with the disease. "If there is a significant other in your life, you guys need to come together with this. For me, that made all the difference."

More information: Learn more about Peyronie's disease from the [U.S. National Library of Medicine](#).

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