

Device for acid-reflux management wraps itself around disease

Donahoe had GERD, or gastroesophageal reflux disease, but it wasn't diagnosed until he was a sophomore quarterbacking his high school football team. That's when a physician, the father of a teammate, spotted him drinking freely from a bottle of the over-the-counter antacid Mylanta at a game and asked why.

"I got into his office, found out what it was and started treating it (with prescription drugs) from there," said Donahoe, now 24, of White Oak, Pa.

Still, despite the drugs, total relief eluded him until this past April, when he underwent a surgical procedure that's still in a clinical trial being conducted at the University of Pittsburgh Medical Center. Since Dr. Jim Luketich implanted the LINX Reflux Management System, Donahoe has felt like the proverbial new man.

"I feel great, like there was nothing done," said Donahoe, who is finally eating anything he wants after years of denying himself such loves as grapefruit and orange juice.

"I would highly recommend it. After several years (of suffering), to be in pain for a couple of hours (after surgery), it's well worth it. I had acid reflux really bad the morning of the surgery. When I woke up, it was gone."

The system is being tested at 15 sites across the nation and two more in Europe. It's a braceletlike device composed of magnetic titanium beads that wraps around and fortifies the lower esophageal sphincter, the valve that connects the esophagus to the stomach. When the valve doesn't close tightly, it leaks stomach acid, and reflux occurs.

Why it happens is a question with multiple answers, said Luketich, director of UPMC's Heart, Lung and Esophageal Surgery Institute.

"Some foods or medications can cause it to leak, and you fill it too full of food, overeating of anything, it can be bad," he said. "One of the risk factors . . . is obesity; it puts too much pressure on the valve. Some thin people get it and there may be a hereditary factor.

"But there's smoking, chewing tobacco, eating fatty foods, drinking two pots of coffee a day. There are things we do that are not good for the valve or the esophagus. . . .

"Most of the time, it can be managed without surgery," he added. "You can lose weight; give up coffee, reduce stress in your life. If that doesn't work, then you can take (over-the-counter) medications like Tums or Maalox, and if those don't work, then you go to a (prescription) drug like Nexium."

And if they don't work, or if they cause bad side effects, or if your insurance won't cover the cost, then you might want to consider surgery, Luketich said.

These days, the most common surgery is a procedure called a Nissen fundoplication. It's done laparoscopically, during which time the surgeon wraps a part of the stomach around the leaking valve to fortify it.

"We probably do them as well as anybody in the world, but what we noticed is that the Nissen is not perfect," he said. "It's not like the initial valve, the one you're born with. It can never be duplicated. . . . It is the gold standard."

The LINX system is a product of Torax Medical, a firm founded in 2002 with the stated mission of creating a better treatment option for patients suffering from GERD.

In some ways and under certain circumstances, it seems to be just that, said Luketich. For example, he said, "This doesn't work for large hiatal hernias." The LINX can only be placed in hiatal hernias less than three centimeters in size.

But for a leaking valve, he said, "In the short run, it seems as good or better as the Nissen. . . . (But) we don't have long-term data."

The device is implanted via the five small incisions of a laparoscopy and it takes only about an hour. Luketich said the patients can go home after an overnight hospital stay.

Donahoe was restricted to a liquid diet for three days, and Luketich asked him not to lift anything heavier than 10 pounds for a month. There were no stitches, Donahoe said, just Steri-strips.

Luketich found two major pluses for the LINX when compared with the Nissen.

"Number one, it's easy to place . . . easier than the Nissen," he said. "That's first and foremost - that it's safe and simple for an experienced surgeon."

He stressed that both the LINX and the Nissen should be done by experienced surgeons because the esophagus is delicate, its blood supply tiny and its nervous system intricate.

"Number two, it does open to allow food to pass down into the stomach," he said. ". . . We measure it before we put it in, and we can add one or two more beads if it's too small or we can take out one or two beads if too loose."

And the downside?

"Sometimes it still is too tight, and a patient says, 'I can't eat flank steak,' or, 'I can't eat my bagel.' I say, 'OK, would you rather have no heartburn or eat what you want?' They ponder that a little bit," Luketich said.

"Also a downside: It is metal, and that means for right now you can't have an MRI."

That's a problem that's being worked on, he said, "but now if you have something" that would require an MRI, "you must get a different diagnostic test, like a sophisticated CT scan. . . . That's a consideration for someone who might have a bad knee or epilepsy or another brain problem."

And one final downside: "We don't know how it's going to work for 10 years. Magnets are infinity; they last a lifetime. . . . Will it remain in position? It is in long-term animal patients and for a couple years in (early human) patients."

And so far so good, for the six patients Luketich has done over the last couple months.

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