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Implanted Devices May Fight Obesity

Tiny Gadgets Stimulate Stomach, Nervous System; Awaiting Trial Results

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A new wave of implantable stomach devices could transform the way doctors approach obesity.

A number of companies are racing to develop implants that zap the stomach or certain nerves with an electrical current, much the way a cardiac pacemaker zaps the heart. The hope is that the electric jolts can help modify eating behavior, possibly by regulating appetite signals or boosting metabolism.

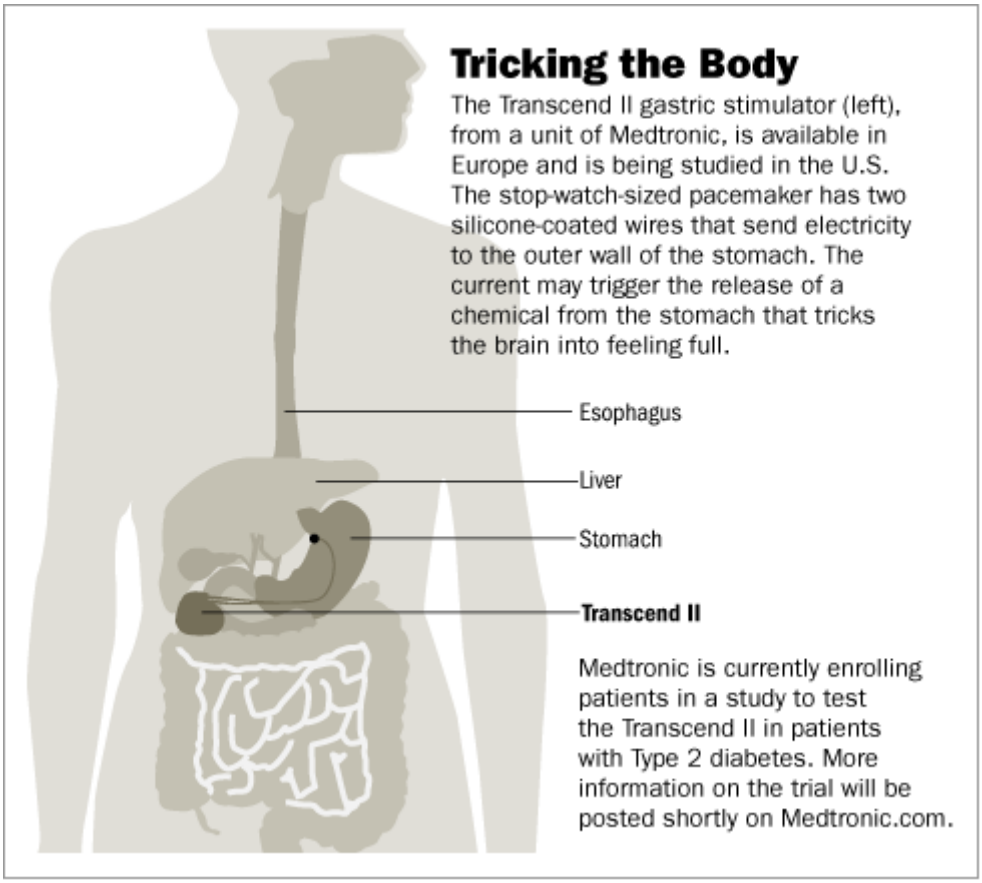
One such device -- known as the Transcend II gastric stimulator -- is already available in Europe and is in clinical trials in this country. A handful of similar electronic implants are in the pipeline, with several clinical trials slated to be launched later this year.

The new gadgets are aimed at severely obese people, and aren't intended to help the merely plump shed a few extra pounds. Researchers are hopeful that the devices -- which can be implanted using minimally invasive surgical techniques -- one day will provide a less-risky alternative to major bariatric surgery.

The emerging field got a boost in June when Medtronic, one of the world's largest medical-device makers, paid $260 million to acquire Transneuronix, the New Jersey-based start-up that developed the Transcend device. The gadget -- which is thought to work by triggering feelings of fullness -- has been on the market in Europe since 2001, and also recently was approved in Canada. But Transneuronix was a small 40-person operation with limited marketing muscle, so the gadget is still relatively unknown.

Now, Medtronic plans to usher the device through the Food and Drug Administration's approval process, with an eye on making it available in the U.S. by 2007. A major clinical trial is under way in this country to test the efficacy of the device for obesity. Medtronic also is recruiting patients for a trial in obese people with Type 2 diabetes, to measure how inducing weight loss affects diabetes symptoms. Such research ultimately could help get health insurance to pay for the device as a diabetes treatment, because insurers sometimes won't cover treatments for obesity alone.

More than 60 million American adults are obese, according to the American Obesity Association, making the condition one of the largest unconquered markets in contemporary medicine. Currently, the most effective treatment for obesity is bariatric surgery, which involves reducing the size of the stomach or bypassing parts of it. But such procedures can cost $20,000 or more, and the risks are high: One in every 200 people who undergoes gastric bypass surgery



dies, by some estimates. That means it typically is reserved only for extreme cases -- so-called morbid obesity.

Patients, doctors and health-care companies are desperate for a simpler, safer alternative that also could treat less-severe cases. Implanting small gastric devices may mean fewer complications than major surgery. Some patients from earlier Transcend trials have had the device for as long as 10 years, and report few side effects, such as devices that "migrate" in the body. Unlike most bariatric surgery, the implants are reversible.

Medtronic estimates that the treatment could cost $15,000 to $20,000, including the device, surgery and hospital stay.

It is too early to know just how effective the electrical implants will be. Doctors involved in preliminary studies, conducted over the past decade at Italian centers and at Tufts-New England Medical Center estimate that the gadget will help only one-third to one-half of obese patients. Binge eaters, for example, might continue eating even with the device. "We have many people who don't listen to the signals of fullness," says Scott Shikora, director of bariatric surgery at Tufts-New England.

In patients who do have success with the device, however, the average patient lost about 40% of excess body weight. That compares with about 40% to 65% of excess weight typically lost through bariatric-surgery procedures.

One potential downside with Transcend is that the battery lasts only about three to five years, so patients would need a new round of surgery every few years to get the device replaced.

Medtronic is just one of many pursuing such implants. Leptos Biomedical of San Diego is developing an obesity implant that delivers an electrical charge to certain nerves. The company says the device stimulates the same part of the nervous system that is activated by exercise, and potentially can help people lose weight by boosting their metabolism. So far, the gadget has been tested on dogs. A small human trial will begin before year end.

EnteroMedics, in St. Paul, Minn., is collaborating with the Mayo Clinic in Rochester, Minn., to test an implant that uses electrical charges to inhibit the main nerve leading to the stomach. The company says cutting off the nerve supply may slow down digestion because the stomach doesn't register the food and start the digestive process. So far the device has shown positive results in pigs, but human trials begin later this year. Interested patients can contact Info@enteromedics.com.

Intrapace of Menlo Park, Calif., is developing a capsule-shaped implant the size of a C-battery that can be inserted in the stomach through the throat. Like Medtronic's Transcend, the Intrapace gadget would deliver electricity to the stomach to trigger feelings of fullness. It is in animal trials.

With promising new obesity drugs on the horizon, some doctors say patients could use an implant to keep their weight under control until the drugs arrive. A number of major pharmaceutical companies -- including Eli Lilly, Merck and Sanofi-Aventis -- have explored compounds for obesity, and a new wave of obesity drugs is expected over the next decade.

"Given all the tremendous advances we anticipate in pharmacological therapies, this could prevent the need for bariatric surgery in all the but most difficult cases," says Mark Gold, a professor of psychiatry and neuroscience at the University of Florida College of Medicine, who is involved in the Transcend trials.

No one is exactly sure how Medtronic's Transcend helps people lose weight. The battery-powered gadget is inserted deep underneath the skin just below the rib cage with a two- to three-inch incision. The device features two wires that connect to the outer walls of the stomach, delivering low-level electrical pulses. The wires are attached during surgery with the help of a laparoscopic camera inserted into the abdomen through a keyhole-sized opening.

The electrical current appears to trigger the release of a "satiety" chemical, which tells the brain that the stomach is full. The electrical pulse also may cause the stomach muscle to relax and distend the way it does when it is full of food, which may trick the brain and the body into feeling full. Once the surgery is complete, a doctor or technician uses a wireless computer to adjust the strength of the charge. The current is set just below the point at which patients start to feel it. (Above that point, patients may experience nausea.)

More information on Transcend's efficacy could come this fall, when the first results of the current trial are released. About a year ago, roughly 200 Americans had the device implanted at eight major obesity centers around the country. The device was turned on in half the patients, and left off in the other half. (Participants don't know whether their device was turned on.) Over the next few months, the study will be "unmasked," and doctors will see whether the patients with the gadget turned on actually lost more weight.

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