Losing Prospects: New procedures hope to treat obesity without the risks of bariatric surgery

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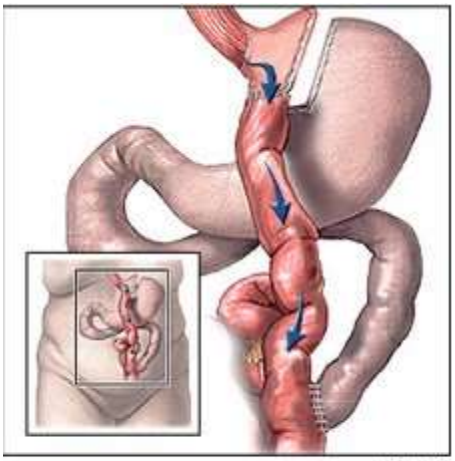
Losing Prospects

New procedures hope to treat obesity without the risks of bariatric surgery

By RON WINSLOW

More than 200,000 Americans each year undergo a major operation called bariatric surgery to treat obesity. But doctors say millions more might opt for treatment if it were less invasive and more patient-friendly.

A host of medical-device companies and doctors are targeting this market with an array of strategies that aim to mimic features of bariatric surgery while reducing the trauma and risk. But human biology, the harsh environment of the digestive tract and uncertainty over regulatory rules all pose daunting hurdles.



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Many patients seek less-aggressive alternatives to Roux-en-Y surgery, the current standard.

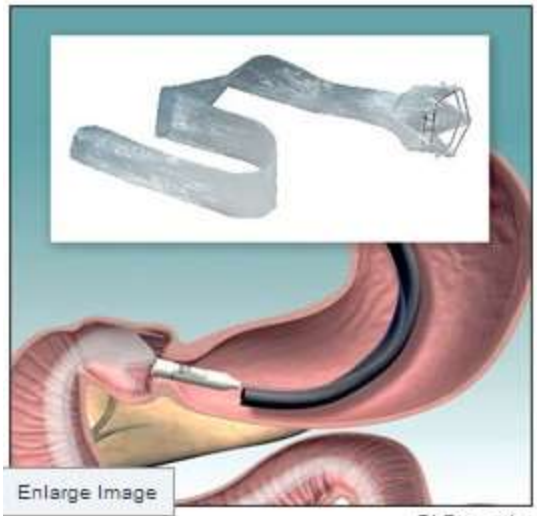
The gold-standard bariatric surgery is called Roux-en-Y gastric bypass, in which surgeons both shrink the stomach and reroute the digestive tract to bypass a portion of the intestines. The benefits include weight loss, improved long-term survival and, for many obese diabetics, control of blood sugar well before they lose significant weight. About 3.6% of patients experience major complications such as abdominal bleeding or blood infections; about one in 1,000—fewer than in gallbladder or hip-replacement surgery—die from the operation.

Many patients opt for less-aggressive surgical approaches, including an adjustable gastric band (which can be reversed) that forms a pouch in the stomach, or a sleeve gastrectomy, in which a portion of the stomach is removed, leaving a tube for food to pass through. Both leave the intestines intact but make patients feel full.

All three of those procedures require incisions. Emerging alternatives—including the three featured below—typically don't. They are performed using an endoscope inserted through the mouth. They don't

require a hospital stay and can be done much faster than surgery. They also don't permanently alter the stomach or any other part of the digestive tract. Indeed, they are designed to be undone within a year.

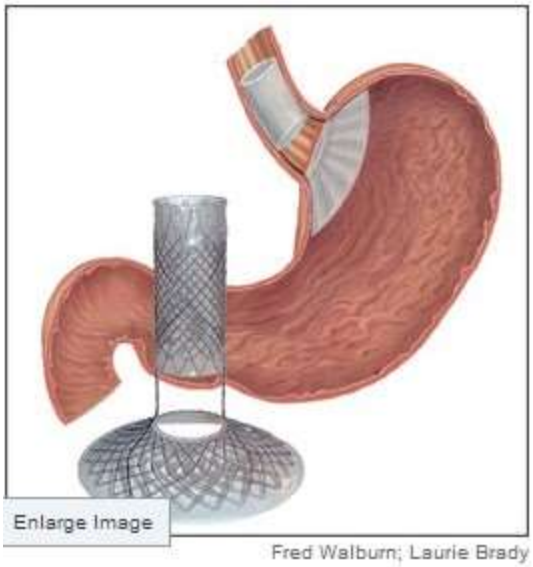
One question is whether a temporary fix will suffice. "If you do a temporary obesity procedure," says J. Chris Eagon, head of bariatric surgery at Washington University in St. Louis, "it's unrealistic to expect that people will be able to keep the weight off that they've lost." Proponents hope patients will make diet and exercise changes to keep weight off; if not, they say, the procedures could be redone.



GI Dynamics

Tube-Shaped Liner: One alternative treatment is the EndoBarrier, developed by GI Dynamics Inc. of Lexington, Mass. It is a tube-shaped device that lines a portion of the intestine just below the stomach to block food absorption. Reflecting studies that show a Roux-en-Y-type effect on blood sugar but a more modest impact on weight, the company is positioning the EndoBarrier first as a treatment for Type 2 diabetes and then for weight loss.

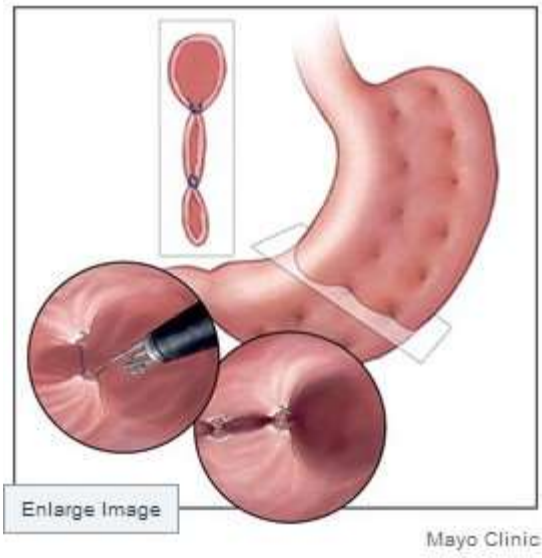
Side effects include occasional irritation and bleeding from barbs that anchor the EndoBarrier at the junction of the stomach and small intestine. The device, deployed in 800 patients so far, is on the market in Australia, Chile, Israel and several European countries. In January, the company launched a 500-patient trial aimed at helping it gain regulatory approval in the U.S. If all goes well, it could be on the U.S. market by 2017.



Fred Walburn; Laurie Brady

Disk and Anchor: In contrast, the Full Sense device is deployed at the top of the stomach. It consists of a disk placed in the stomach and tethered to a cylindrical stent that anchors the device in the esophagus. The disk pushes against the top of the stomach, tricking nerves and gut hormones into signaling that the stomach is full even when food isn't present, says Randal Baker, a surgeon in Grand Rapids, Mich., who invented the device.

Dr. Baker hasn't published peer-reviewed results, but he has told medical audiences that the procedure has been performed on more than 50 patients, and on average they have lost weight faster than typically occurs with Roux-en-Y surgery, without significant side effects. BFKW LLC, a Grand Rapids startup, hopes to launch the device in Europe early next year; U.S. availability is years away.



Narrowing Down: At the Mayo Clinic, in Rochester, Minn., Christopher Gostout aims to mimic the effect of a sleeve gastrectomy, creating the stomach tube by stapling off instead of cutting out a large portion of the stomach. All six patients treated so far have lost weight with minimal side effects, Dr. Gostout says. No new devices are used in the procedure, so regulatory approval isn't required. The tube can be tightened or patched if the staples lose their hold in the digestive process. If all goes well in a current study, Dr. Gostout says, the procedure could be offered at Mayo as soon as the end of the year.

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