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Wednesday, June 3, 2009

# Procedure hailed for major weight loss



Lissa Haynes of Spencer is the recipient of a new weight-loss surgery called transoral gastroplasty. She is shown with Dr. David Cave and Dr. John Kelly at UMass Memorial Medical Center in Worcester. (T&G Staff / PAUL KAPTEYN)

By Aaron Nicodemus TELEGRAM & GAZETTE STAFF  
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**WORCESTER** — Lissa Haynes struggled for more than a decade to lose the same 40 pounds.

Ms. Haynes, 55, of Spencer, had tried every kind of diet and every conceivable exercise regimen. Nothing worked. Classified as obese, Ms. Haynes suffered from constant backaches, high cholesterol, and severe sleep apnea.

After reading a newspaper advertisement, Ms. Haynes decided to participate in a clinical trial for a new, nonsurgical procedure offered at UMass Memorial Medical Center.

Called TOGA, for transoral gastroplasty, the procedure involved manipulating a patient's stomach from the inside. While the patient is under general anesthesia, a tiny camera and flexible stapling device are inserted through the throat and down the esophagus. With the stapler, a

### TOGA procedure

The TOGA (transoral gastroplasty) procedure, designed by Satiety, Inc., is a noninvasive treatment for morbid obesity that limits stomach capacity to give patients a feeling of fullness after a small meal. The procedure works by inserting flexible devices into the stomach through the mouth.



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thumb-sized pouch is created in the walls of the stomach, at the stomach's opening.

The benefits to the TOGA procedure are obvious. There are no scars, as there are no incisions. Complications - from infections, hernias, or leaks in the digestive tract - that occur during traditional obesity surgeries are rare. Instead of two to eight weeks, recovery time is three to five days.

"There is some discomfort. It gives you a sore throat. Some people experience some pain below the solar plexis," said Dr. Kanishka Bhattacharya, associate director of endoscopy at UMass Memorial, assistant professor of medicine at the University of Massachusetts Medical School, and the principal investigator of the study.

Following the procedure, food passes more slowly through the pouch on its way to the stomach. The patient eats slower, feels full after a smaller meal, and eats less.

In a recent interview, Ms. Haynes was effusive about the procedure's effectiveness.

"It's the best thing I've ever done," she declared. Since she had the surgery in January, Ms. Haynes has lost 48 pounds.

"I feel 20 years younger," she said.

Since having the procedure, Ms. Haynes said, she eats more slowly, taking at least 30 minutes to finish a meal. When she goes out to dinner, she never finishes her entree, and often eats it for lunch over several days.

"After a couple of bites, I start to feel full," she said.

Ms. Haynes has also joined a running club and participates in an exercise "boot camp" in Lake Park with her daughter twice a week.

"I've changed my whole lifestyle," she said.

The TOGA procedure is still experimental, and has not been approved by the Food and Drug Administration.

Satiety Inc., the California medical device manufacturer that paid for the clinical trial, hopes the FDA will approve the procedure within the next 18 months to two years.

Dr. Bhattacharya said the procedure has shown promise. In Europe and Mexico, where trials on the TOGA procedure have been conducted for several years, patients have lost about 40 percent of their excess weight.

"There are a huge group of people afraid of the word surgery," he said. "If this works, it will be a very good addition to the available treatments for obesity."

UMass Memorial was one of nine facilities nationwide using this technique, and the only one in New England. A total of 13 procedures were conducted in Worcester from January to May, when the trial ended.

"It's what the future may hold for obesity treatments," said Dr. John J. Kelly, chief of general surgery and co-director of bariatric surgery at UMass Memorial, as well as an associate professor of surgery at UMass Medical School.

He said that improvements in medical devices and in surgical techniques have made "natural orifices" surgery a reality.

For years, doctors have tried to minimize the pain of surgery and aid recovery by performing surgery through small slits rather than large incisions. Small cameras and ever-improving medical devices have allowed doctors to navigate through the body on a video screen, rather than opening up the patient's body.

More than 220,000 patients had surgery for obesity last year in the United States, according to the American Society for Metabolic and Bariatric Surgery. The most popular operation is gastric bypass surgery, in which the stomach is shrunk and the intestines rearranged. Another available treatment is gastric banding, in which a loop is tightened around the top of the stomach. Both types of procedures have proven weight loss results and are FDA-approved.

In order for the clinical trial to address the placebo effect, a third of the patients in the trial had "sham" surgery. Just before each surgery, doctors opened an envelope to determine which surgeries were real and which were not. In the sham surgeries, devices were put down the patient's throat but no pouch was created.

Ms. Haynes was one of two patients who signed up knowing she would receive the TOGA procedure.

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All the patients will be monitored for a year. After the year is over, patients receiving the sham treatments will be allowed to return and receive the actual TOGA procedure.

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