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CEDARS-SINAI SURGEONS PERFORM FIRST TWO INCISION-FREE PROCEDURES FOR OBESITY IN THE WESTERN UNITED STATES

LOS ANGELES (Aug. 20, 2008) – Doctors at Cedars-Sinai Medical Center in Los Angeles have performed the first two non-surgical procedures in the Western United States that restrict the size of the stomach to treat obesity. The experimental procedures were part of the TOGA Pivotal Trial, a Phase III, multi-center study evaluating an incision-free procedure using the TOGA® System (transoral gastroplasty). Like conventional “open” surgery or laparoscopic band procedures to treat obesity, the TOGA procedure is designed to alter a patient’s anatomy to give a sense of fullness after a small meal. The difference is that the investigational technique delivers the treatment through the mouth, without any incisions.

Using direct endoscopic visualization with specialized instruments passed into the stomach through the mouth, doctors performed the procedures on August 18. The patients were both women – age 34 and 40, respectively.

According to Edward Phillips, M.D. and Gregg Kai Nishi, M.D., investigators of the study at Cedars-Sinai and surgeons in the hospital’s Center for Weight Loss Surgery, the first procedure took one hour and 49 minutes and the second procedure took 90 minutes. “Everything went exactly as planned,” Phillips said.

This investigational device represents a potential new approach to weight loss surgery. “If this non-surgical procedure provides results that are comparable to those of conventional weight loss surgeries, it may provide a good option for patients who need to lose a significant amount of weight but do not wish to have surgery,” said Phillips, who is Executive Vice-Chairman of the Department of Surgery and Chief of General Surgery at Cedars-Sinai.

In the TOGA procedure, a set of flexible stapling devices are delivered through the mouth into the stomach, with the staples creating a restrictive pouch. As food enters the stomach, it goes into this pouch, giving patients the feeling of “being full” after eating less.

In a pilot study being conducted at medical centers in Belgium, Mexico and Italy, 93 subjects have had the procedure since February 2006. Data presented at this year’s Digestive Disease Week on 29 of these patients showed that before the procedure, patients weighed an average of almost 130 pounds over their ideal body weight. The 27 subjects who reached the six-month interval had lost almost 40 percent of their excess body weight, and the nine patients who reached the 12-month interval had lost almost 50 percent of their excess weight.

“That’s less than we typically see with gastric bypass surgery,” said Nishi. “However, when compared to laparoscopic or open surgeries, endoscopic procedures generally result in quicker recoveries, shorter hospital stays, and fewer complications.”

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Both of the Cedars-Sinai patients were given general anesthesia when receiving the TOGA procedure and stayed overnight for observation. However, Phillips anticipates that the procedure will eventually be performed on an outpatient basis with sedation rather than general anesthesia, depending on the study's results.

Patients in the study will be evaluated regularly for at least one year. All study-related medical care is provided at no charge, and patients receive medically supervised nutrition counseling. Because these were the first two patients at Cedars-Sinai and were training cases, both knew they were getting the actual treatment, but for comparison purposes during this blinded, randomized study, one of every three volunteers will be a control patient, receiving anesthesia and an endoscopic evaluation of the stomach, without the TOGA procedure.

If the study shows that the procedure is effective, these control patients will be offered the TOGA procedure after 12 months. Investigators will evaluate weight loss and monitor obesity-related health problems such as type 2 diabetes, cholesterol levels and hypertension. If the restrictive pouch becomes bigger over time, as sometimes happens in weight loss surgery patients, it may be possible in the future to decrease the size of the pouch with this new generation of devices.

The TOGA study will investigate the technique in at least 275 patients at centers across the United States. Investigators at Cedars-Sinai are planning to enroll about 20 volunteers into the trial. Volunteers must be 18 to 60 years old and have a BMI of 40 or greater (100 pounds or more overweight). Some lighter patients (BMI 35-40) may be considered if they have type 2 diabetes, high blood pressure or other illnesses associated with obesity. Patients with a recent heart attack, stroke, chest pain or severe reflux disease are not eligible.

This study is evaluating the safety and effectiveness of the investigational procedure. The TOGA Pivotal Study protocol has been approved by the FDA (via an investigational device exemption) with the understanding that results will be used to seek approval to market the TOGA System.

For more information about the TOGA study, patients or their families may call 1-866-678-8399 or visit online at www.togaclinicalstudy.com.

Manufactured by Satiety, Inc., the TOGA System is an investigational device and is not currently approved by the U.S. FDA. The TOGA Pivotal Trial is funded by Satiety, Inc.

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