

Oral 'Speed Bump' Slows Eating; Aids Weight Loss

BY FRAN LOWRY
Orlando Bureau

NEW ORLEANS — An oral device that fits in the mouth much like a retainer could help overweight individuals eat more slowly and, in the process, eat less and lose weight, according to a poster presented at the annual meeting of NAASO, the Obesity Society.

Almost half of those who ate with the device in their mouths lost at least 5% of their body weight at the end of a 20-week, open-label, randomized study, said Dr. Mitchell Roslin, chief of the bariatric surgery program at Lenox Hill Hospital in New York City.

The study, which was carried out at four centers in the United States, randomized 108 adults aged 18-49 years who had a body mass index (BMI) of between 26 kg/m² and 36 kg/m² to one of two groups. In one of the groups, 41 subjects used the oral device and received counseling on nutrition, and in the other group, 67 controls received the nutrition counseling alone. The counseling was presented on a DVD.

The subjects in both groups were demographically similar. They were weighed at baseline and at the end of the study, and palatal impressions were taken for those who were randomized to receive the oral device to optimize its comfort and fit, Dr. Roslin said.

After 20 weeks, nearly half of those in the experimental group (20 subjects) had lost at least 5% of their body weight, compared with almost 5% (3 subjects) in the control group, he reported.

Those who wore the oral device while they ate two of their daily meals had the greatest weight loss, an average of 13.7 pounds. Those who wore it for one meal a day lost an average of 8.0 pounds. Weight loss for the control subjects averaged 0.6 pounds, Dr. Roslin reported.

The device contained a chip, or sensor, to let providers know how often it was used. "If you ... tell me you haven't lost any weight, I can plug in the device and see how many times you have actually worn it. If you've only worn it once, how can it help you?" Dr. Roslin said.

The device works best if patients are motivated, he added.

"Obesity comes from a caloric imbalance and the only way to maintain weight loss is through behavioral change. This device helps with behavioral change. Whether you use [it] to stop you from wolfing down your food, or whether you have an operation, the results you obtain are ultimately up to you. This device is tolerable for motivated patients, but it's not going to overwhelm a person who is not motivated to change his or her behavior. It's a tool, and like any other tool, it has to be used effectively."

Dr. Roslin said he also believes that the oral device, which does not yet have a name, will help people achieve better weight loss than any of the currently available pharmaceuticals—without side effects.

The manufacturer of the device, Atlanta-based Scientific Intake, plans to make a submission to the Food and Drug Administration for approval to market it as a low-risk device.

"It makes intuitive sense that if you

place a speed bump in the mouth, you are going to make people more conscious of their eating behavior. This is what behavior modification is all about. It is making people think about what they are doing so that they can reflect," Dr. Roslin said. "If you can break the fast-eating habit, you can make people eat less, and this is what we have seen in our study."

Dr. Roslin disclosed that he has received shares in Scientific Intake for his advisory role as medical officer to the company. ■

High expectations

for lowering

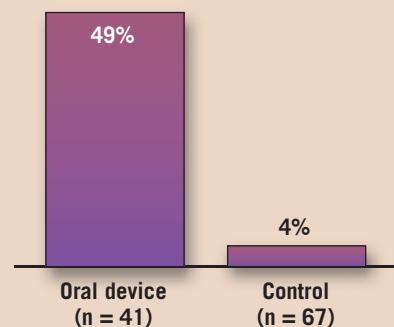
very high triglycerides (≥ 500 mg/dL)

Important Safety Information:

1. LOVAZA is contraindicated in patients who exhibit hypersensitivity to any component of this medication.
2. Before instituting LOVAZA therapy, it should be confirmed that TG levels are consistently abnormal.
3. LOVAZA should be used with caution in patients with known sensitivity or allergy to fish.
4. The patient's TG, LDL-C and ALT levels should be monitored periodically during LOVAZA therapy. In some patients, LOVAZA increased LDL-C. LOVAZA therapy should be withdrawn in patients who do not have an adequate response after 2 months of treatment.
5. Some studies with omega-3-acids demonstrated prolongation of bleeding time, which did not exceed normal limits and did not produce clinically significant bleeding episodes. Patients receiving treatment with both LOVAZA and anticoagulants should be monitored periodically.
6. There are no adequate and well-controlled studies in pregnant women. Use LOVAZA during pregnancy only if the potential benefit justifies the potential risk to the fetus; and use with caution when administering LOVAZA to breastfeeding women.
7. LOVAZA was well-tolerated in controlled studies. The most common adverse events reported were: eructation, infection, flu syndrome, dyspepsia, rash, taste perversion, and back pain.
8. Please see full prescribing information.

References: 1. Lovaza Prescribing Information. Liberty Corner, NJ: Reliant Pharmaceuticals, Inc; 2007. 2. Data on file, Reliant Pharmaceuticals, Inc. 3. Ginsberg HN. Insulin resistance and cardiovascular disease. *J Clin Invest*. 2000;106:453-458. 4. Stalenhoef AFH, de Graaf JD, Wittekoek ME, Bredie SJH, Demacker PNM, Kastelein JJP. The effect of concentrated n-3 fatty acids versus gemfibrozil on plasma lipoproteins, low density lipoprotein heterogeneity and oxidizability in patients with hypertriglyceridemia. *Atherosclerosis*. 2000;153:129-138. 5. Garg R, Vasamreddy CR, Blumenthal RS. Non-high-density lipoprotein cholesterol: why lower is better. *Prev Cardiol*. 2005;8:173-177.

Percentage of Adults Who Lost At Least 5% of Their Body Weight



Notes: Based on a 20-week study of adults who had a BMI between 26 kg/m² and 36 kg/m². All subjects received nutrition counseling. Source: Dr. Roslin

ELSEVIER GLOBAL MEDICAL NEWS

Reliant
PHARMACEUTICALS, INC.

Reliant Pharmaceuticals, Inc.
Liberty Corner, NJ 07938

© 2007 Reliant Pharmaceuticals, Inc.

RLOV-C1005

August 2007