

Fighting against obesity one bite at a time

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Small Bite Inc. CEO Denis Mulder displays his company's device, which is designed to help people lose weight by making them take smaller bites, ultimately reducing the amount of food they eat. The Haverford company hopes to start patient clinical trials in Philadelphia early next year.

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Americans perennially try to lose weight. They try diets. They try pills and supplements. Some even opt for surgery to make their stomachs smaller.

But many of these methods don't work long-term, or, in the case of bariatric surgery, not everyone is ready for such a drastic step.

Now one company, Small Bite Inc., thinks it may have an answer.

The tiny Haverford start-up makes a device that fits in the mouth and restricts jaw movement, causing wearers to take smaller bites and consume less food - thus losing

weight. It is intended to be used for six to nine months.

Many people eat too fast, and, as a result, take in too many calories before realizing they have had enough. It takes about 20 minutes from the start of eating until the brain senses fullness, researchers have found.

Small Bite's orthodontic device has been tested on 50 patients in Europe. The company is talking with the U.S. Food and Drug Administration about starting patient clinical trials early next year in Philadelphia.

Ben Franklin Technology Partners of Southeastern Pennsylvania, which allocates state funds to promising early-stage technology, announced Sept. 4 that it was investing \$300,000 in Small Bite. "We approved it based on the idea that this probably did fill a niche in obesity treatment," said Jennifer Hartt, Ben Franklin's director of life sciences investments.

Obesity has reached epidemic proportions globally, according to the World Health Organization. About two-thirds of American adults, or 133 million people, are overweight or obese. One-third of them, or 63 million, are obese, according to the National Center for Health Statistics.

"Food intake starts at the mouth. We thought, what can we do about it?" said Small Bite's cofounder and chief executive officer, Denis Mulder.

Small Bite's device is a form of behavior modification. It is designed to teach people to eat in smaller bites.

"You can eat anything, but you have to cut everything in very small pieces," said Mulder, who is in preliminary discussions with weight experts at Temple University and the University of Pennsylvania about conducting the patient studies in Philadelphia.

He also has talked with the community clinic at Albert Einstein Medical Center in North Philadelphia.

The idea for the device came from Jan Renders, a 330-pound patient in Amsterdam who said he had been overweight all his life and had tried many diets.

Renders could have opted to have his jaw wired shut in order to shed pounds, but, as a singer in a band, he wanted to be able to open his mouth - to sing.

He had an idea of attaching "elastics" to his upper and lower molar teeth that restricted how wide he could open his mouth - and the amount of food he could put in.

Renders approached Amsterdam orthodontist René Linders, and they designed a

device, made of dental polymer and attached with orthodontic adhesive to the upper and lower molars. The polymer strands are connected to a chain that rests against the lower front gum.

If the mouth opens too wide, the chain presses against the lower gum, "which is unpleasant, so you don't do it," Renders said. The device does not put pressure on the teeth or jaw.

After nine months wearing it, Renders said he had lost 130 pounds, going from 330 pounds to 200, a weight that he maintains today. "I have continued to eat in small bites," he said. "I've had a few weight fluctuations, like with a good vacation, but it's the difference of four kilograms - it's nothing."

But Renders had a caution. "This device is not a holy thing," he said. "If you have the will - the wish - to lose weight and you cannot do it yourself, it's a wonderful help."

Mulder, a native of the Netherlands, came to Boston in 1997 and later ran business-software companies in Malvern and Princeton. He said he met Renders and Linders through "a friend of a friend." They decided to commercialize the device in the United States, and founded Small Bite in 2006, investing their own money.

The company has a way to go before getting its device onto the U.S. market. Mulder, who runs Small Bite out of a home office in Haverford, is consulting with an obesity expert at Penn on FDA protocol for the patient trials. He said he has found orthodontic manufacturers and suppliers for materials used in the device.

The clinical trials in Philadelphia will enroll 130 people, ages 18 to 65, who will wear the device initially for six months. The results then must be analyzed and submitted to the FDA. A second study will follow up with patients to see if they keep the weight off.

To qualify, participants must be 26 to 43 pounds overweight or more, based on their height.

If Small Bite's product were to be approved by the FDA, it would be the first oral weight-loss device approved by U.S. regulators, Mulder said.

"The unfortunate truth is that most treatments for obesity are pretty effective in the short term, but not so effective in the long term," said Gary Foster, director of the Center for Obesity Research and Education at the Temple University School of Medicine.

"So the greater the variety of treatments available to people who are trying to manage their weight, the better," Foster said. "This may be one approach that offers some relief, but it does await further investigation in large clinical trials."

Michael Goldfinger, who runs an internal-medicine clinic at Albert Einstein Medical Center, said Small Bite's device was "a great idea because it's a way of promoting a behavioral change that people are otherwise not able to do on their own."

Attaching a device to the mouth is less drastic than gastric-bypass surgery. It's "short-term and reversible," he said. "If the patient is not able to deal with it psychologically, you just take it out and you're done."

The device, which is installed and removed by an orthodontist, was tested in 50 patients at an Amsterdam orthodontic clinic. Patients wore it between three months and six months. They lost between 10 and 15 percent of their body weight, Mulder said.

"People can eat what they want. Of course, we advise them to eat healthy," Mulder said. "We don't tell them they have to follow a diet."

The biggest problem was irritation in the mouth, similar to that from wearing braces, which usually went away after a few weeks. Two or three of the 50 stopped wearing the device because of discomfort.

"We are not claiming we will solve the obesity problems of every single patient," Mulder said. "For about 80 percent of the population, it's portion control. Portion control and portion distortion is one of the main problems in obesity."

"The concept is very simple. Everyone understands that food enters the body through the mouth and not in the stomach. If we can help a lot of people, and make our business a success, what better combination can you have?"

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