

Full Sense Device

New endoscopic stent can lead to 100% EWL



Stent leads to mean EWL of 80% at six months

15-minute installation has not yet resulted in any significant complications or revisions

Device to be released next year in Europe, with US release to follow

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Pete Myall - Online editor, Bariatric News

The printed version of this article from issue 12 of Bariatric News incorrectly stated that the Full Sense device operates by directly stimulating the vagus nerve. It in fact operates by stimulating neuro and humoral elements to induce satiety. The article has been updated to reflect this.

A simple endoscopic stent is being developed which will be able to be fit in 10-15 minutes and can lead to startling rates of weight loss, claim its designers.

The Full Sense device, which its designers Sentinel Group of Michigan, USA, hope will become available in Europe late this year or early next year, has demonstrated a median excess weight loss (EWL) of 80% in a six-month trial. This evidence was backed up by a later randomised control trial and a follow-up crossover trial. Some patients had their devices removed early after achieving 100% EWL.

An earlier trial in three patients with a mean BMI of 44 demonstrated a 28.5% EWL in six weeks. The device works by constantly stimulating neuro and humoral feedback mechanisms and thereby inducing satiety.

Presenting at the 2nd International Symposium for Non-invasive Bariatric Techniques in Lyon, Dr Randal Baker, Assistant Professor of Surgery for Michigan State College of Human Medicine and inventor of the device, claimed that it has achieved these results without any significant complications or need for revision.

“We expected to see a 5 or 6% difference between [the study group and the control group], but we saw a tremendous weight loss.” *Dr Randal Baker*

Baker said of the device, “We’ve had no non-responders. Patients continue to lose weight, no exceptions, until the device is taken out.”

He suggested that the apparent efficacy of the device, along with its non-invasive nature, simple installation, and low cost, would “open up the market” of the 99% of eligible US patients who do not undergo bariatric surgery every year, particularly among obese children and teenagers.

Speaking in 2009 following the first successful human implants, Sentinel vice president Dr James Foote said the technology is “Potentially the greatest step forward in the battle against obesity since the inception of bariatric surgery.”

Device

The Full Sense device consists of a conical component which sits in the cardia, and a cylindrical stent that is placed just above the gastroesophageal junction. The two components are attached by a tether that passes through the junction, which causes the conical component to place upwards pressure on the top of the stomach.

Patients with the Full Sense device fitted experience a simulated feeling of satiety, said Baker, leading them to eat less.

While early designs for the device required laparoscopic assistance to install, the current design can be installed completely endoscopically in an outpatient setting, and is easily reversible. Baker said that further adaptations are currently being developed to make the device even quicker and easier to install.

While other bariatric techniques, like the gastric band, are believed to achieve early satiety by stimulating the vagus nerve, said Baker, they do this in response to the presence of food in an artificially created small pouch. This pouch ordinarily stretches over time, requiring the presence of more food to induce satiety and reducing the technique’s efficacy, meaning that patients’ weight loss slows and eventually stops.

The Full Sense device, on the other hand, works by directly and constantly stimulating neuro and humoral elements even without the presence of food, meaning that the stretching of the stomach does not take place, and the patient will continue to lose weight until the point that the device is taken out.

The designers of the device believe that, unlike as with other devices, the patient's metabolic rate does not drop as they lose weight. Patients are placed on a liquid diet for two weeks after installation, but after that, they are not placed under any dietary restrictions.

While the direct stimulation leads to impressive rates of weight loss, it also means that the Full Sense device is not currently a permanent solution for patients, as it does not present a method of stabilizing patients at a healthy weight – if left in for too long, the device could possibly lead to a patient becoming underweight. However, said Baker, Sentinel are currently trying to develop an adjustable version which can lower the pressure that the device places on the stomach.

Baker noted that the patients who have been caught in the early stages of obesity lost weight the fastest while using device, and were the patients who were slowest to put weight back on once the device was removed. However, no patient in any trial has yet failed to respond or lose an unsatisfactory amount of weight.

Early results also show the device to be effective at resolving comorbidities such as diabetes and high blood pressure.

Development

The inspiration for the device came from a patient who was suffering from multiple complications following a Roux-en-Y gastric bypass and came to Baker with a chronic stricture at the gastrojejunostomy. Baker placed a stent across the stricture to hold it open, and when the patient returned to his office two weeks later, he was surprised to find that she was losing weight despite eating a solid food diet.

When she told him that her weight loss was due to her no longer feeling hungry, he hypothesized that the stent was putting pressure against the top of the stomach, and her brain was interpreting the signal as a sign that her stomach was full of food.

Sentinel developed this concept into a number of prototypes of the Full Sense device. While the device was initially attached to the esophageal wall using barbs, it caused ulcers, so the tether concept was developed.

Laparoscopic assistance was initially required to get the tether suture across the angle of His, but the group developed a tool that could do it endoscopically.

Initial studies were performed using dogs. “We expected to see a 5 or 6% difference between [the study group and the control group],” said Baker, “but we saw a tremendous weight loss.”

Equally surprising was the animals' reaction to the operation. While dogs normally become lethargic and depressed when losing heavy amounts of body weight, the animals in the study remained happy and lively. While the study guidelines called for the animals to be euthanized at 20% weight loss, the vets felt that the animals were doing so well that they allowed the study to continue.

Sentinel

The company developing the device is miniscule by medical technology standards. Rather than developing in a lab in a multinational corporation or a university, Sentinel work out of a suburban home in Grand Rapids, Michigan.

The company have not yet published any peer-reviewed articles on their studies. They attribute this to the fact that, rather than attracting money from venture capitalists, they are able to raise the development funds they need from friends and family.

Baker says that while working with institutional funders would require them to continually publish in order to raise their profile with new investors, their low funding requirements allow them to continue working without the constant need to publish. “We’re taking a slightly different path on this,” he said.

Once the device has achieved CE status, the company will concentrate on winning FDA approval, allowing them to release the device in the USA.