

# Researchers test obesity, diabetes tool

October 22 2013, by Jay Price

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University of North Carolina-Chapel Hill researchers are testing a promising device that fights two of the most common health problems that Americans face - obesity and diabetes.

The EndoBarrier is a thin sleeve made of a plasticlike material that lines part of the upper [digestive tract](#) so that food simply passes through that section rather than undergoing full digestion.

A team led by Dr. Laura Young of the UNC Diabetes Care Center is part of a nationwide, 500-patient, 20-site study of the device. It has begun seeking local volunteers to participate.

The EndoBarrier has been approved for use in Europe and various countries elsewhere, including Australia, Chile and Israel. It must undergo a large-scale test here, though, before the U.S. Food and Drug Administration will allow it to be marketed in this country.

Diabetes, which is characterized by problems controlling high [glucose levels](#) in the blood and often closely tied to obesity, is a big cause of heart disease, stroke and complications that include loss of eyesight and kidney failure.

In [patients](#) elsewhere, the Endo-Barrier has substantially reduced patients' weight and lessened and even reversed the symptoms of Type 2 diabetes, by far the most common type.

The device's effects are similar to those triggered by gastric bypass

surgery. One advantage, though, is that it doesn't require surgery. Instead, it is put in place via the mouth and throat by a relatively simple procedure involving a flexible instrument.

The procedure usually takes about 15 minutes, Young said. And unlike surgery, it's easily reversible if it causes problems.

If it is effective, she said, the device could also reduce a patient's need to use various medications for diabetes.

More than 650,000 people in North Carolina have been diagnosed with diabetes, according to the U.S. Centers for Disease Control and Prevention. Nationwide, the number of new cases has been climbing since 1992 and has nearly tripled since then.

The study is focused on the device's effect on Type 2 diabetes, Young said, with [weight loss](#) a secondary interest.

Once the EndoBarrier is installed, improvements in patients' diabetes symptoms often come within days, before the gradual weight loss that the device causes even kicks in, according to earlier studies and results with patients in other countries.

The effects on [diabetes](#) appear to come by not just blocking the body from digested food but also altering hormonal signals that part of the digestive tract sends to other parts of the body, Young said.

"We think it's a way to help the body respond to the food that comes through it in a different way," she said.

In earlier, smaller studies, it was effective helping patients controlling [blood glucose](#) levels and effective in reducing weight by often double-digit percentages.

It also caused various problems for some patients, including abdominal pain, bleeding and obstructions by the device.

The EndoBarrier was developed by GI Dynamics Inc., a 10-year-old company based in Lexington, Mass.

Dr. David Maggs, the chief medical officer for the company, said that both the device and the technique of putting it in place have been improved since the early studies. Those changes have significantly reduced the complications, he said.

Another issue with the device is whether its effects last. The EndoBarrier will remain in study participants only for 12 months, the standard period for use in patients elsewhere in the world.

Researchers will continue to follow patients' conditions for several weeks after the device is removed, Young said, in hopes of learning more about what happens after it is out.

At this point, more than 1,000 patients have had the device implanted, Maggs said. After it is taken out, there seems to be a "legacy effect" that keeps blood glucose at improved levels and weight down, but there is only limited data so far on that.

If the trial proves that the [device](#) works and is safe, it is expected to be widely available by 2017.

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