MedicalXpress

Mayo Clinic first to implant device to solve fecal incontinence

June 7 2016

A clinical team on Mayo Clinic's Florida campus is the first to offer four patients with long-term fecal incontinence a new and potentially long-lasting treatment—a small band of interlinked magnetic titanium beads on a titanium string that successfully mimics the function of the anal sphincter.

At this point, Mayo Clinic is the only medical center that has surgically implanted this device, known as the Fenix Continence Restoration System. In December 2015, the system received U.S. Food and Drug Administration approval under a humanitarian device exemption, which requires approval for patient use by a hospital's Institutional Review Board (IRB). The IRB at Mayo Clinic is the first and, as yet, the only center to approve use of the device.

The issue of fecal incontinence, or accidental bowel leakage, is not unusual. It can affect more than 20 percent of women over 45, says Paul Pettit, M.D., a female pelvic medicine and reconstructive surgery specialist at Mayo Clinic. "The condition can be debilitating due to social isolation, depression, loss of self-esteem and self-confidence.

"If a patient does not improve through use of less invasive techniques, our only option has been a colostomy," says Dr. Pettit, who performed the four surgeries. "This device now offers a new option that restores function, and we are happy to be able to offer it."

The operation itself lasts about 45 minutes and requires an overnight

hospital stay.

Most patients with fecal incontinence—a syndrome that involves unintentional loss of solid or liquid stool—are women, and often the cause is childbirth, when the muscles and nerves near the anus are damaged, Dr. Pettit says.

When the system is implanted, the string of magnetic titanium beads is placed around the anal canal in the closed position. Increased intra-abdominal pressure opens the beads to allow for passage of stool. The magnets then spontaneously close.

The device works immediately after surgery and does not require any activation by the patient or adjustments by a physician, according to the manufacturer, Torax Medical Inc., in St. Paul, Minnesota.

Provided by Mayo Clinic