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Mayfield Clinic Neurosurgeons Are First in Cincinnati To Implant Artificial Disc in Patients In FlexiCore Clinical Trial at University Hospital

CINCINNATI, Ohio – Neurosurgeons at the Mayfield Clinic are the first in Cincinnati to implant an artificial disc in patients suffering from degenerative disc disease of the lower back, the Clinic announced Tuesday. Three patients have been treated with the FlexiCore artificial disc as part of a clinical trial at University Hospital.

The all-metal artificial disc, designed to relieve severe lower back pain and preserve mobility, is being implanted in patients who have not responded to conservative treatment. In the past such patients would have undergone spinal fusion, a surgical procedure in which two or more vertebrae are fused together to immobilize the spine.

The multi-center artificial disc study, called the FlexiCore Intervertebral Disc Clinical Trial, seeks to determine whether symptom relief provided by the FlexiCore artificial disc is better, worse, or the same as fusion surgery and whether patients receiving the FlexiCore disc still have motion of their vertebrae. Patients who have undergone fusion have little or no motion at the fusion site. Both treatments -- disc replacement and fusion -- are expected to relieve pain and the symptoms of nerve irritation, while halting the progression of any present symptoms related to the spinal cord.

Dr. Charles Kuntz, IV, a Mayfield Clinic neurosurgeon and Director of Spine and Peripheral Nerve Surgery at the University of Cincinnati (UC), is a principal investigator in the FlexiCore trial. His co-investigators are **Dr. William Tobler**, a Mayfield neurosurgeon, the Director of Neurosurgery at Christ Hospital, and an associate professor of neurosurgery at UC; and **Dr. Robert Bohinski**, a Mayfield neurosurgeon and an assistant professor of neurosurgery at UC. The three neurosurgeons are affiliated with The Neuroscience Institute at UC and University Hospital.

The FlexiCore trial is for patients between the ages of 18 and 60 who (1) suffer significant back pain and disability associated with degeneration of the disc at a single vertebral level in the lower back and (2) have been unresponsive to conservative (non-surgical) treatment for back pain for a minimum of six months.

The spine is made up of bones (vertebrae) that are stacked on top of each other. Between each vertebra is a disc. Healthy discs, tough and rubbery on the outside and jelly-like on the inside, act like shock absorbers and allow the spine to bend and twist during exercise and everyday activities. Discs can degenerate with age, losing their flexibility and their ability to cushion the spine.

The FlexiCore artificial disc, manufactured by Stryker Corp. of Kalamazoo, Mich., is made entirely of metal. Shaped like a ball, it rests between two supporting plates. Neurosurgeons implant the ball and plates after removing the degenerative spinal disc.

Because the FlexiCore disc is an investigational device, the federal government

requires a study of its safety and effectiveness before it can become generally available to the public. As such, patients cannot request that the disc be implanted. Those who participate in the FlexiCore trial have a two-in-three chance of being treated with the artificial disc. Of every three patients enrolled in the trial, two are randomly selected to receive the artificial disc and one is randomly selected to be treated with fusion. Participating patients will be asked to return for follow-up visits so that doctors can assess the success of the two procedures.

For more information about the FlexiCore study, [click here](#).

Patients or families wishing to enroll in the FlexiCore trial in Cincinnati can contact Suzanne Kempisty-Clover of the Mayfield Clinic at (513) 558-5387 or suzanne.kempisty-clover@uc.edu.

The Mayfield Clinic is recognized as one of the nation's leading physician organizations for clinical care, education, and research of the spine and brain. Mayfield, which is affiliated with the UC Department of Neurosurgery, includes 16 neurosurgeons and treats 20,000 patients from 35 states and a dozen countries in a typical year. Mayfield's neurosurgeons are active participants in important clinical trials and have pioneered surgical procedures and instrumentation that have revolutionized the medical art of neurosurgery for brain tumors and neurovascular diseases and disorders.

University and Christ hospitals are part of the Health Alliance, an integrated health care delivery system that also includes the St. Luke Hospitals, Jewish Hospital, Fort Hamilton Hospital, and the physicians of Alliance Primary Care. To view other Health Alliance news releases, go to www.health-alliance.com/pressroom.

The Neuroscience Institute is a regional center of excellence based at University Hospital and supported by nine neuroscience specialties of the UC College of Medicine. The Institute is dedicated to patient care, research, education, and the development of new medical technologies. To view other Neuroscience Institute news releases, go to www.leadingtheadvance.com/newsflash.nsf/tnews.