

OKLAHOMA SPINE & BRAIN INSTITUTE

Cervical artificial disc:

a motion sparing alternative or treatment of neck pain.

by Dr. Frank Tomecek, M.D.

Neck pain affects millions of Americans every year. People between the ages of 35 and 65 are most likely to experience neck pain at some point in their lives. Neck pain is a common cause of disability in people under the age of 50. With this prominence of neck pain, the decade from 2000 to 2010 has been nationally recognized as the decade of the spine. This decade has been devoted to extensive research on treating common problems that affect the cervical spine and cause neck pain.

Historical Treatment

In the past, the most common treatment for cervical spine problems involved either decompressing the neural elements and/or stabilizing the cervical spine with a fusion. Annually, over 100,000 cervical spinal fusions are done in the United States alone. Over the past few years, there has been an evolution in the treatment of neck pain. Spine surgeons are relying less on stabilizing damaged motion segments and opting for a new approach involving preservation of spine mobility.

Revolutionary Device

The Oklahoma Spine and Brain Institute has the unique opportunity of being involved in an FDA IDE study involving the Mobi-C® cervical disc prosthesis. It is one of many new emerging technologies that focuses on removing a damaged disc or arthritic changes in the cervical spine that can cause pain while adding support and preserving the mobility of the spine. The study is a prospective, randomized, multi-center investigation in which the study device will be compared to the control treatment, a conventional anterior cervical discectomy and fusion in accordance with a Smith-Robinson procedure. The study is randomized in a 2 to 1 ratio with two patients receiving artificial disc replacement to every fusion patient. The patients are followed for 2 years after the operation.

This study will evaluate the overall success rate of the Mobi-C® cervical disc prosthesis as compared to the control in the treatment of patients with symptomatic degenerative disc disease and with herniated discs of the cervical spine causing radiculopathy or myeloradiculopathy at one or two adjacent levels. Previous artificial discs in clinical trials have only been studied for single level disc disease whereas the Mobi-C® with it's newer and improved technology can be used and studied for two adjacent level discs.

Spinal Fusion Shortcomings

The Oklahoma Spine and Brain Institute feels that neck pain that is not associated with progressive loss of function should be treated conservatively, if at all possible. After failure of conservative treatment, the past gold standard of care for degenerative

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*Published by
Oklahoma Spine and Brain Institute,
6802 S. Olympia Avenue, Suite 300
Tulsa, Oklahoma 74132
918.749.0762
www.osbi.net*

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disc and disc herniation was spinal fusion through an anterior cervical approach. Most spinal surgeons acknowledge that cervical spinal fusion has many shortcomings. Several articles have been published which show even in perspective studies a significant percentage of adjacent level degeneration and disc herniation next to a previously fused level. Many patients require second and even third operations to treat adjacent level disc disease. Studies show that between 10 and 15% of patients suffer degenerative changes either spondylosis, stenosis or herniated discs next to previously fused levels and these numbers increase as the time progresses from the fusion. Patients who have had fusions may have pain at the bone graft site, pseudoarthrosis and failed fusion (commonly seen in smokers) and pain due to loss of mobility and stiffness in the neck. All of these conditions can lead to further operations and prolonged disability. The Oklahoma Spine and Brain Institute acknowledges that all patients deserve to have different options for spinal treatment and some patients are definitely candidates for motion sparing operations that may avoid the pitfalls of spinal fusion.

Mobi-C®



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Selection Criteria

While artificial disc replacement technology is very promising, not everyone with intractable neck pain is a candidate for artificial disc surgery. To be considered a candidate for the Mobi-C® artificial disc study, the patient must meet specific criteria.

This is a FDA IDE study and if the patients fits the inclusion criteria and has no exclusion criteria they may be a candidate for the use of this technology in a study setting.

The Mobi-C® cervical prosthesis is a product of LDR. The disc consists of a mobile plastic core that sits between two cobalt chrome endplates that are coated with hydroxyapatite. The cobalt chrome plates lock into the spine with metal teeth. According to research by LDR, the disc materials have been tested mechanically in the lab and should be able to withstand standard wear and tear in the human body. In comparison to spinal fusion surgery, potential benefits of this technology include quicker recovery time, more spinal mobility after surgery, less stress of adjacent discs and no need to harvest and use bone graft or any bone graft substitute materials.

The surgical technique for the artificial disc involves an anterior cervical incision that is made from the midline to the midborder of the sternocleidomastoid muscle. After the disc is exposed and the area held with self retaining retractors, the disc is removed in

Inclusion Criteria

- ✓ Be between the ages of 18 and 69 years.
- ✓ Have a diagnosis of radiculopathy or myeloradiculopathy of the cervical spine with pain, paresthesia or paralysis and a specific nerve root distribution from C3 through C7.
- ✓ Have neck or arm pain, decreased muscle strength, abnormal sensation including hypesthesia and/or abnormal reflexes.
- ✓ Be symptomatic at one or two adjacent levels from C3 to C7.
- ✓ Have pathology that is diagnosed radiographically by either decreased disc height on X-rays, CT or MRI and/or degenerative spondylosis or stenosis on CT or MRI or disc herniation in the cervical spine seen on CT or MRI.
- ✓ Be unresponsive to nonoperative conservative treatment consisting of rest, heat, physical therapy, chiropractic care and/or analgesics for approximately 6 weeks.
- ✓ Have had no prior surgery at the operative level and no prior cervical fusion procedure at any level.
- ✓ Be able and willing to discontinue all use of nonsteroidal anti-inflammatory medications from 1 week before surgery to 3 months after the surgery.
- ✓ Be in overall good health with no signs of infection especially at the operative site or in the disc space.
- ✓ Have no history of hepatitis or other communicable diseases.

Exclusion Criteria

- ✓ Previous trauma to the C3 to C7 levels resulting in significant bony or discoligamentous cervical spine injury.
- ✓ If the patient has severe disc height loss or severe facet joint disease.
- ✓ If the patient has severe osteoporosis or osteopenia on DEXA scan.
- ✓ Reported active malignancy.
- ✓ Symptomatic degenerative disc or cervical spondylosis and stenosis at more than two levels.
- ✓ Marked cervical instability on resting lateral or flexion or extension views that includes translation of the cervical spine greater than 3.5 millimeters and/or greater than 11 degrees of angular difference of adjacent levels.
- ✓ High-dose steroid use and smoking.

“Cervical artificial disc preserves mobility of spine and treats neck pain”

“Previous artificial discs in clinical trials have only been studied for single level disc disease whereas the Mobi-C® with it’s new and improved technology can be used and studied for two adjacent level discs.”

a conventional fashion. Then instead of placing a bone graft in the interbody space and a plate on the spine, the artificial disc is inserted in the interbody space with special instrumentation.

Experience and Care

All of our surgeons at the Oklahoma Spine and Brain Institute have completed training in the placement of this artificial disc. Dr. Steve Gaede, M.D., F.A.C.S. is the chief investigator of this study at our institute. Patients entering this study must be aware that just like undergoing a cervical discectomy and fusion there are potential risks and complications of this surgery. Most of the potential risks of artificial disc surgery are common to many of the other types of spinal fusion surgeries such as infection, bleeding, nerve injury and anesthetic complications. Patients entering this study must also be aware that they may be randomized to the control group which receives the standard of care an anterior cervical discectomy and fusion with a bone bank graft and a plate. This operation has been performed by all the surgeons at the Oklahoma Spine and Brain Institute.

Long term patient monitoring and follow-up is an essential component of the Mobi-C® cervical disc prosthesis study. All patients are frequently followed with examinations, x-rays and testing for 2 years. With this technology we hope to offer patients a unique opportunity of having a shorter hospital stay, a much faster return to work time, no requirements for rigid cervical collars and the opportunity to maintain proper disc function and spinal segment mobility. Often patients with spinal fusion complain of stiffness in their neck and loss of mobility which affects their quality of life. In this FDA study and in our own experience it appears that cervical artificial disc placement is equally effective in relieving discogenic neck pain when compared to spinal fusion. However, there certainly is a role for spinal fusion in the treatment of neck pain. Neck pain that is caused by instability, spondylolisthesis, fractures or tumors would not be able to be treated by artificial disc technology. The artificial disc is not a stabilizing device but it is one that preserves motion and adds support to the spine. Also, severe deformity of the spine would not be treatable with cervical artificial disc.

The surgeons at the Oklahoma Spine and Brain Institute are expertly trained in the indications and contraindications for the use of cervical artificial disc replacement and in spinal fusion technology. We are proud to be the only spinal surgery group in Oklahoma to offer to you a cervical artificial disc for treatment of intractable neck pain caused by cervical disc herniation or cervical spondylosis and stenosis. We are also proud to serve you and your patients and have all of the available options and new technologies which can be used to treat your patients’ spinal problems. To find out more information about this procedure or to find out more about degenerative disc and cervical pain, please feel free to visit our website www.osbi.net.

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Oklahoma Spine & Brain Institute announces our newest team member, Rene Fernette, PA-C. She joins us from Michigan and has over twelve years experience in neurosurgery. We are excited to have her!

Join us in welcoming **Rene Fernette, PA-C**

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We have available space at 6802 S. Olympia Avenue. Conveniently located at Hwy 75 and 71st Street, this state of the art facility was awarded the “ABC 2006 Excellence in Construction Award” by Associated Builders and Contractors, Inc., Oklahoma Chapter. For more information please contact Scott Morgan with Coury Properties at (918) 583-0201.

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