

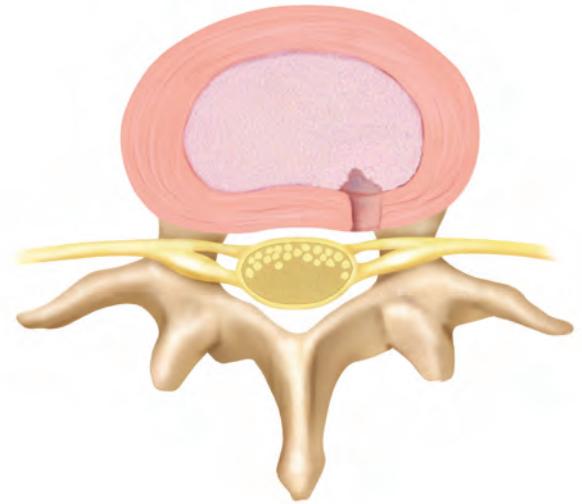
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OKLAHOMA SPINE & BRAIN INSTITUTE

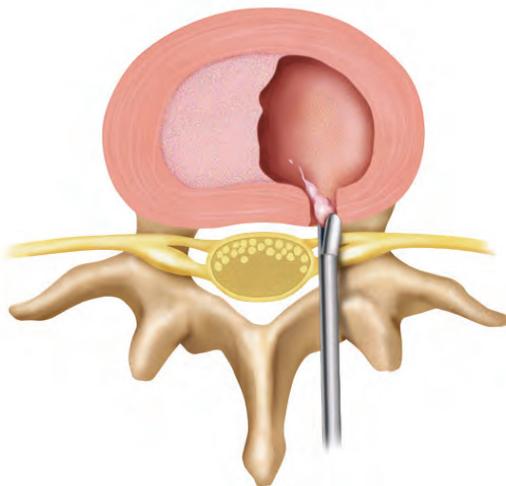
PREVENTING RECURRENT DISK HERNIATIONS IN THE LUMBAR SPINE

by Frank J. Tomecek, M.D.

At some point in their lives, four out of five people will have to deal with back pain. The most common cause of back and radicular leg pain is a herniated lumbar disk. Previously, the standard of care for a herniated disk was to remove the portion of the disk applying pressure on the nerve root. This procedure is referred to as a microdiscectomy and typically requires the surgeon to perform a small laminotomy, retract the nerve root, make an incision in the outer layer of the disk called the annulus fibrosus, and remove the herniated part of the inner portion of the disk known as the nucleus fibrosus. Unfortunately, making an opening in the annulus, also known as an annulotomy, usually leaves a significant defect through which the nucleus can re-herniate. The discectomy procedure offers many patients relief of back and leg pain after the procedure. However, statistics show approximately 30% of patients have recurrent pain following a lumbar discectomy, and an estimated 10% to 15% of patients require reoperation. It should be mentioned that in some cases, a herniated disk involves a tear through the entire annulus. Therefore, a more extensive opening of the annulus is not required, and all that is necessary is to remove the free fragment of the nucleus that is herniated. Previously, there has been no easy method to repair the defect in the annulus, whether it is a complete tear through the annulus and herniation or whether it is secondary to an annulotomy made by the surgeon. Typically in the past, surgeons commonly left the annulus to heal on its own. Leaving an annular defect has been felt to increase the risk of recurrent disk herniation.



Minimal Discectomy



Aggressive Discectomy

designed to reapproximate the soft tissue of the annulus is the Xclose™ Tissue Repair System. This system was developed by Anulex Technologies, Inc.

Pain and recurrence notwithstanding, there are over 800,000 lumbar discectomy procedures performed worldwide each year to treat disk herniations in the lumbar spine. Most patients recover in a matter of weeks; but sometimes it takes months to completely recover, and some patients have early recurrence of back pain and/or leg pain. With annular disk repair which is now available, a microdiscectomy procedure with repair, provides a new method for treating the compromised tissue of the annulus fibrosus following a discectomy procedure. After removing the offending portion of the disk that is impinging the nerve root, surgeons are able to reapproximate the soft tissue of the annulus, to facilitate the healing process and prevent reherniation of the nucleus. The device designed to reapproximate the soft tissue of the annulus is the Xclose™ Tissue Repair System. This system was developed by Anulex Technologies, Inc.

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Inclose Surgical Mesh System

For larger defects in the annulus, a patch is available named the Inclose™ Surgical Mesh System. After annular repair, most patients are able to walk the same day, begin physical therapy almost immediately, and return to normal exercises within a few days after surgery. They are also able to return to work sooner with less fear of recurrent disk herniation.

Anatomy of Xclose

The Xclose Tissue Repair System itself is comprised of sterile braided material made of polyester. When two of the bands are placed on either side of the annular defect or incision in the annulus, they can easily be drawn together to reapproximate the tissue. Essentially, the annulus is reapproximated with tension bands that are tensioned and then knotted together. The construct is provided sterile and is preloaded on a disposal needle-delivery system.

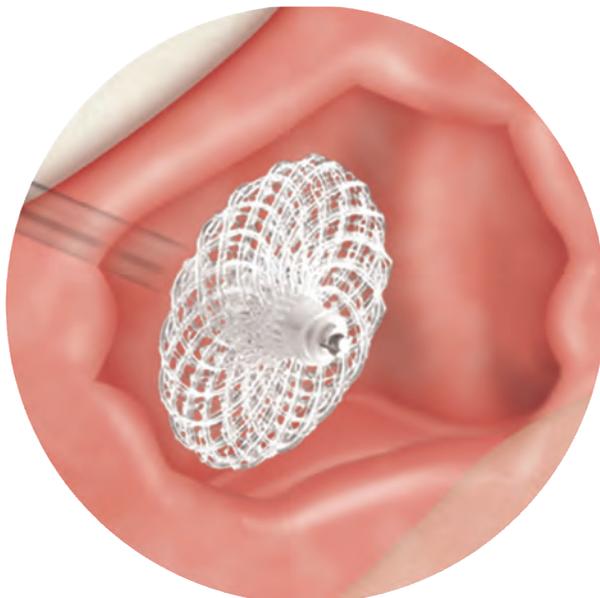
Using the Xclose system only adds a few minutes to the operative procedure. It is fast, easy, and repairs the annulus reliably. It does not add any increased risk to the procedure.

Recurrent Pain after Discectomy

Approximately 30% of patients have recurrent back pain following lumbar discectomy. Many of these also have radicular leg pain. An estimated 15% of patients require reoperation. In some situations, patients have progressive degeneration of the disk, which ultimately leads to bony endplate inflammation, osteophytes, and progressive lumbar stenosis and spondylosis. Frequently, these patients who have progressive degeneration after a discectomy, go on to have a spinal redo decompression and fusion for stabilization. The Xclose system is not effective in preventing progressive degeneration of the disk. It is effective in preventing one of the other common causes for recurrent back and leg pain, which is recurrent herniation of the disk. One way we surgeons can prevent progressive degeneration of the disk, is to remove as little disk as possible, and only as much as is necessary to decompress the nerve. Removing too much disk will lead to collapse of the disk, stress on

the facet joints, and progressive degeneration of the spine.

Therefore, it is a good thing not to disturb a patient's normal anatomy very much. With a minimal discectomy, there is less risk of reherniation, and the patient can return to activities earlier because a majority of the normal structural support of the disk is still intact. Before, 15% of patients would develop recurrent disk herniations after discectomy. The Xclose system significantly decreases the risk of recurrent disk herniation.



Inclose Surgical Mesh System

Repair System not only prevents recurrent pain after surgery due to its decreased potential for recurrent disk herniation, but also by repairing the annular defect. This decreases the potential for leakage of chemicals within the nucleus and center of the disk, that could irritate the posterior annulus and the nerve root. Thus, it may be effective in both preventing recurrent pain due to recurrent mechanical pressure on the nerve, and chemical irritation of the nerve.

Microdiscectomy and annular repair with the Xclose system can be performed endoscopically or microscopically. If there is a large herniation and large annular defect, a patient may not be a candidate for annular repair. We at the Oklahoma Spine & Brain Institute have been trained in the use of the Xclose system, and are fully aware of its indications and contraindications. The Xclose system and annular repair can be used in the vast majority of patients with normal disk herniations, and especially in younger patients with active lifestyles who have strong annular tissue. In the elderly, where the disk is severely degenerated, annular repair may not be indicated or effective.

Benefits of Xclose

There are two theories behind radicular pain with a disk herniation. One is a mechanical theory where pressure on the nerve root causes pain. Another is a chemical theory where substances within the disk, such as prostaglandins and substance P, leak out of the disk and irritate the posterior annulus which is innervated and

the nerve root as well with the chemicals that are mentioned which can elicit pain. There are theories that the Xclose Tissue

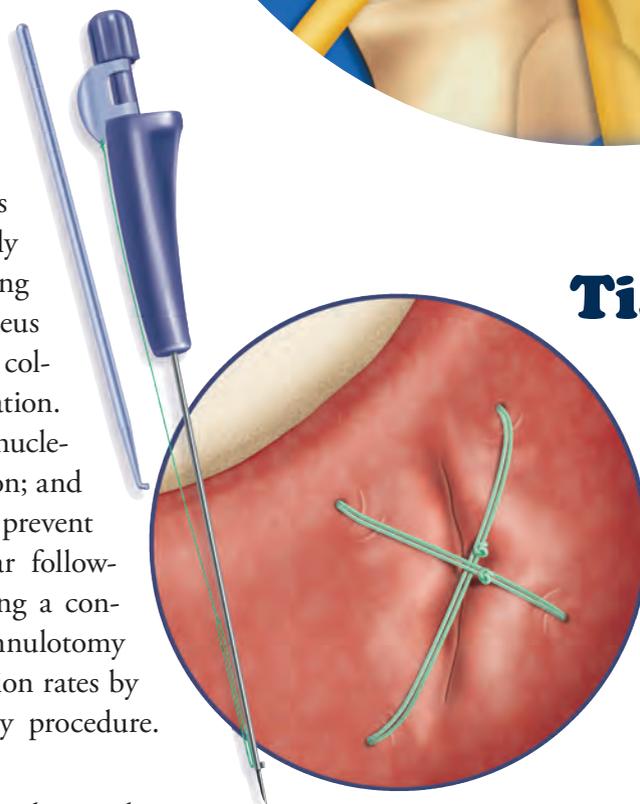
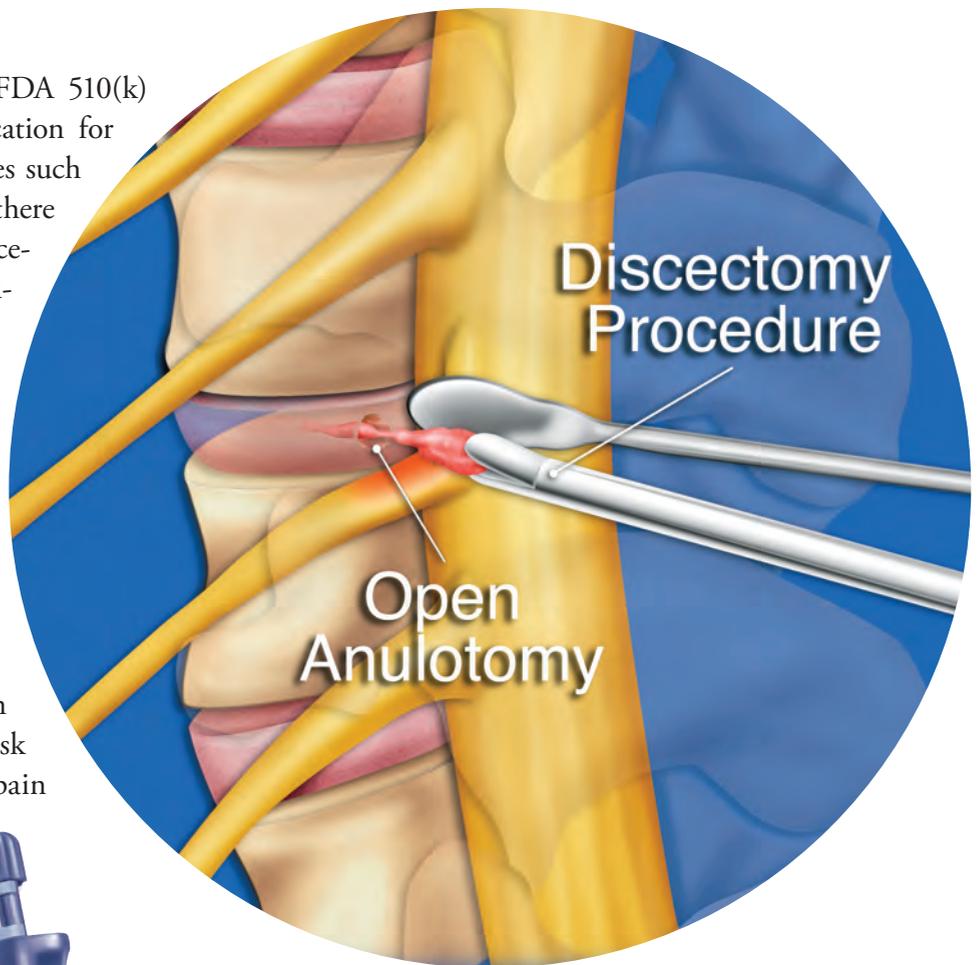
Studies and Guide lines

The Xclose Tissue Repair System received FDA 510(k) clearance in September 2006, with an indication for use in soft tissue approximation for procedures such as general and orthopedic surgery. To date, there have been approximately 4,000 Xclose procedures performed in the United States. Studies are currently underway to compare recurrent disk herniation frequency in controlled situations with no annular repair, to patients who have an annular repair.

In the past, spine surgeons frequently performed an aggressive discectomy, creating a large opening in the annulus, and removing a large volume of nucleus pulposus to reduce the risk of reherniation. Unfortunately, this can result in disk height collapse, progressive disk degeneration, and recurrent mechanical back pain due to instability of the spine, that eventually results in reoperation. To guard against disk collapse and progressive degeneration, surgeons now often perform more of a minimal discectomy that focuses on removing as little of the nucleus as possible. Only the herniated disk is removed, freeing the nerve root. Preserving the nucleus has been shown to reduce disk height collapse and progressive disk degeneration. However, leaving the majority of the nucleus may increase the risk of reherniation; and this is where annular repair can help prevent recurrent back surgeries. A two-year follow-up study with 254 patients, including a control group, showed that a slit-style annulotomy and annular repair, reduced reoperation rates by 68% following a lumbar discectomy procedure.

In conclusion, microdiscectomy and annular repair offer a more complete solution for radicular pain and disk herniations. This simple procedure preserves the nucleus and minimizes reherniation. Enabling a less extensive removal of the nucleus, helps to maintain disk height for normal spinal mechanics. Restricting nucleus material from re-extruding with annular repair, reduces disk reherniation. Annular repair also minimizes leakage of chemical mediators that may reduce inflammation and scar formation. Scar formation after discectomy is another

cause for recurrent back pain and leg pain. Until now, there has been no easy, efficient way for spine surgeons to repair an annular defect following discectomy. Leaving the annulus unrepaired may potentially result in reherniation, persistent pain, and need for reoperation. We at the Oklahoma Spine & Brain Institute feel that preventative spinal surgery is extremely important to minimize the possibility of patients requiring multiple spinal surgeries. To learn more, feel free to contact us on our website, www.osbi.net or visit Anulex online at www.anulex.com.



X Close Tissue Repair System

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Here at Oklahoma Spine & Brain Institute, we are pleased to have served Eastern Oklahoma for the past 38 years from our Tulsa office. Since adding our Bartlesville office 14 years ago, we have recently added satellite offices in Miami, Pryor, Sallisaw, and Cushing, to grow and excel with high quality medical care.