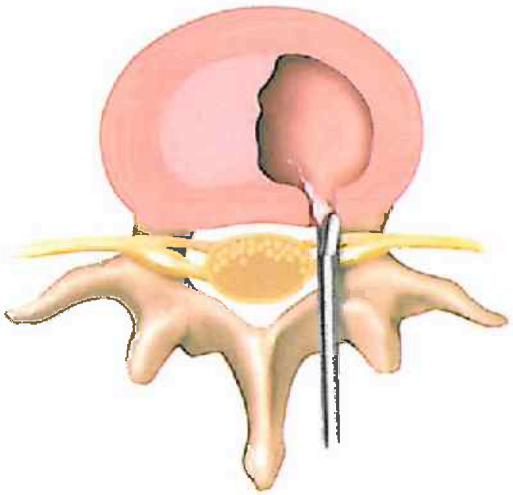
WINTER UPDATE 2010

Advanced Orthopedic Center

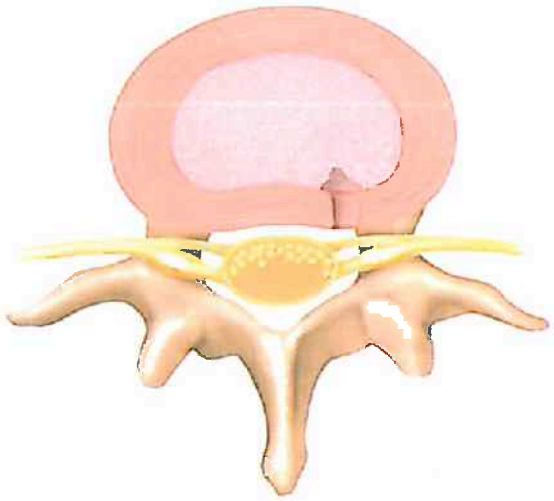
PREVENTING RECURRENT DISC HERNIATIONS IN THE LUMBAR SPINE

By Samuel J. Hess, 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 disc. Previously, the standard of care for a herniated disc was to remove the portion of the disc applying pressure on the nerve root. This procedure is referred to as a discectomy and typically requires the surgeon to perform a small laminotomy, retract the nerve root, make an incision in the outer layer of the disc called the anulus fibrosus, and remove the herniated part of the inner portion of the disc known as the nucleus fibrosus. Unfortunately, making an opening in the anulus, also known as an annulotomy, usually leaves a significant defect through which the nucleus can re-herniate. A discectomy offers many patients relief of back and leg pain after the procedure. However, statistics show that approximately 30% of patients have recurrent pain following a lumbar discectomy, and an estimated 10% to 15% of patients require a re-operation. Previously, surgeons commonly left the anulus to heal on its own. Leaving an anular defect has been known to increase the risk of recurrent disc herniation.



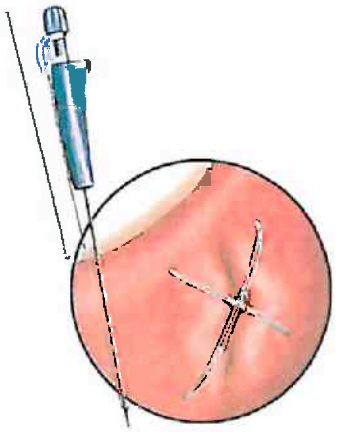
Aggressive Discectomy



Minimal Discectomy

Pain and recurrence notwithstanding, there are over 800,000 lumbar discectomy procedures preformed worldwide each year to treat disc herniations in the lumbar spine. Most patients recover in a matter of weeks. Although sometimes it takes months to completely recover and some patients have early recurrence of back pain and/or leg pain. Anular disc repair provides a new method for treating the compromised tissue of the anulus fibrosus following a discectomy procedure. After removing the offending portion of the disc that is impinging the nerve root, surgeons are able to re-approximate the soft tissue of the anulus to facilitate the healing process and prevent re-herniation of the nucleus. The device designed to re-approximate the soft tissue of the anulus is the Xclose™ Tissue Repair System. This system was developed by Anulex Technologies, Inc.

Xclose Tissue Repair System



Anatomy of Xclose™

The Xclose™ Tissue Repair System is comprised of sterile braided material made of polyester. When two tension bands are placed on either side of the anular defect or incision in the anulus, they can easily be drawn together to re-approximate the tissue and close the defect. The construct is provided sterile and is preloaded on a disposable needle-delivery system.

Using the Xclose™ System only adds a few minutes to the operative procedure. It is fast, easy, and repairs the anulus 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 patients also have radicular leg pain. An estimated 15% of patients require re-operation. In some situations, patients have progressive degeneration of the disc, which ultimately leads to bony endplate inflammation, osteophytes, lumbar stenosis, and spondylosis. Frequently, these patients go on to have spinal redo decompression and fusion for stabilization. The Xclose™ System is not effective in preventing progressive degeneration of the disc but it can be effective in preventing one of the other common causes for recurrent back and leg pain, which is recurrent herniation of the disc. One way surgeons can prevent progressive degeneration of the disc is to remove as little disc material as possible and only as much as is necessary to decompress the nerve. Removing too much disc material can lead to collapse of the disc, stress on the facet joints, and progressive degeneration of the spine.

Therefore, it is beneficial to not aggressively disturb a patient's normal anatomy. With a minimal discectomy, there is less risk of re-herniation, and the patient can often return to activities earlier because a majority of the normal structural support of the disc is still intact. Previously, 15% of patients would develop recurrent disc herniations after a discectomy. The Xclose™ System can potentially decrease this risk of recurrent disc herniation.

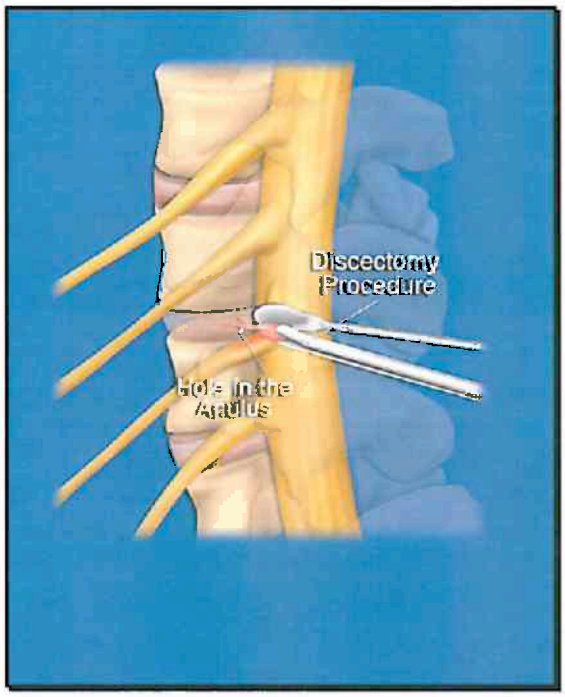
Benefits of Xclose™

There are two theories behind radicular pain with a disc herniation. One is a mechanical theory where pressure on the nerve root causes pain. Another is a chemical theory where substances within the disc, such as prostaglandins and substance P, leak out of the disc and irritate both the posterior anulus and the nerve root with chemicals that can elicit pain. There are theories that the Xclose™ Tissue Repair System not only prevents recurrent pain after surgery due to its decreased potential for recurrent disc herniation, but also by repairing the anular defect. This decreases the potential for leakage of chemicals within the nucleus and center of the disc, which can irritate the posterior anulus and the nerve root. Thus, Xclose™ may be effective in preventing recurrent pain due to recurrent mechanical pressure and chemical irritation of the nerve. Microdiscectomy and anular repair with the Xclose™ System can be performed endoscopically or microscopically. If there is a large herniation and large anular defect, a patient may not be a candidate for anular repair. At Orthopaedic Associates of St. Augustine our Spine Team has been trained in the use of the Xclose™ Tissue Repair System and is fully aware of its indications and contraindications. Anular repair with Xclose™ can be used in the vast majority of patients with normal disc herniations, especially in younger patients with active lifestyles who have strong anular tissue. In the elderly, where the disc is severely degenerated, anular repair may not be indicated or effective.

Studies and Guidelines

The Xclose™ Tissue Repair System received FDA 510(k) clearance in September 2006, with an indication for use in soft tissue approximately for procedures such as general and orthopedic surgery. To date, there have been over 6,000 Xclose™ procedures performed in the United States. Studies are currently underway to compare recurrent disc herniation frequency in controlled situations with patients with no anular repair, to patients with anular repair.

In the past, spine surgeons frequently performed an aggressive discectomy, creating a large opening in the anulus, and removing a large volume of nucleus pulposus to reduce the risk of re-herniation. Unfortunately, this can result in disc height collapse, progressive disc degeneration, and recurrent mechanical back pain due to instability of the spine, eventually resulting in re-operation. To guard against disc 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 disc is removed, freeing the nerve root. Preserving the nucleus has been shown to reduce disc height collapse and progressive disc degeneration. However, leaving the majority of the nucleus may increase the risk of re-herniation; this is where anular 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 anular repair, reduced re-operation rates by 68% following a lumbar discectomy procedure.



In conclusion, microdiscectomy and anular repair offer a more complete solution for radicular pain and disc herniations. This simple procedure preserves the nucleus and minimizes re-herniation. Enabling a less extensive removal of the nucleus helps to maintain disc height for normal spinal mechanics. Restricting nucleus material from re-extruding with anular repair reduces disc re-herniation. Anular 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 anular defect following discectomy. Leaving the anulus unrepaired may potentially result in re-herniation, persistent pain, and need for re-operation. At Orthopaedic Associates of St. Augustine we 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.advanceorthopediccenter.com or visit Anulex Technologies, Inc. at www.anulex.com.

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