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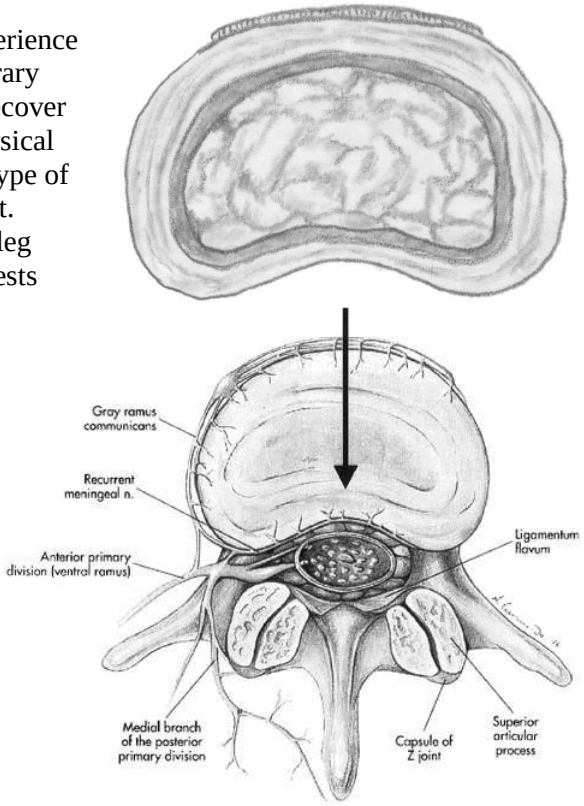
INTRODUCTION

The annular tear or fissure is one of the most misunderstood and underdiagnosed conditions of the lumbar spine Nonetheless, it is one of the more common causes of chronic low back pain in orthopedic spine medicine today. I have called this condition "the great masquerader" because it masquerades as so many other types or causes of back pain. It is commonly misdiagnosed as a back strain, lumbosacral strain/sprain, facet syndrome, sacroiliac syndrome, or herniated disc.

One problem with this condition is that the patient may experience some improvement with conservative treatment on a temporary basis, but then fails to fully recover. The patient does not recover from chiropractic and osteopathic manipulation or from physical therapy. Depending on the extent of the condition and the type of annular tear, the patient may also become exercise intolerant. Such patients often have chronic pain, including peripheral leg pain, yet MRIs, CAT scans, and other common diagnostic tests may appear normal. They are frequently looked at with suspicion by physicians because they fail to demonstrate any significant abnormality on diagnostic imaging.



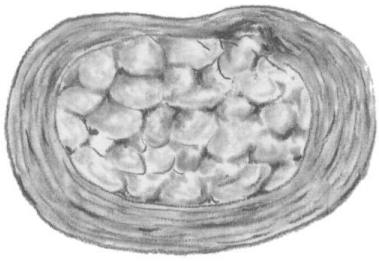
This problem is further complicated by the fact that there are so many medical, osteopathic, chiropractic, and physical therapy professionals who are not trained or experienced in recognizing the various annular tear syndromes that present clinically. There are, however, practitioners who *do* recognize this condition, have developed the diagnostic skills to recognize it, and are more comfortable treating it.

This article has been written to help you sort through the maze of choices in the journey to recovery. It will also

provide you with a means of becoming an informed consumer. This is recommended reading for any patient who has chronic back pain. The condition of the annulus and its affect on motion and stability of the spinal segments is actually at the heart of most mechanical causes of back pain.

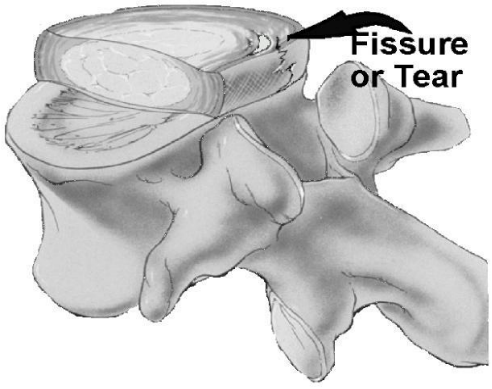
The Anatomy of the Intervertebral Disc

The disc is made up of two primary structures. The first is the *nucleus pulposus*, the center of the disc. This region is softer, less organized. I often say it has the consistency of chicken fat! The other portion of the disc is the *annulus fibrosis*, a well-organized series of concentric, laminated, fibrous rings that surround the nucleus (as shown in the pictures to the right.) The nucleus is mobile within the disc. (For more information on this, I refer you to the article on internal disc derangement.) In brief, the *nucleus pulposus* of the disc dynamically moves forward and back during flexion and extension movements. When you bend forward, the vertebral segments close in the front and push the fatty material to the back of the disc. When you bend backwards, the vertebral segments close at the posterior and the nucleus is pushed toward the center of the disc. These movements can be used clinically.



Of critical importance is the fact that there is a rich nerve supply in the outer fibers of the annulus of the disc.[1] This portion of the disc is capable of producing significant back pain. The drawing above provides an illustration of a normal-looking disc in a cross-sectional view. Over time, as stresses that have been placed on the disc accumulate, the stress will break down the annulus. The annular rings break down and crack or tear.

It may surprise you to know that, once the disc is torn or a fissure begins to develop (as seen in the picture to the right), the disc has a poor healing potential and typically does not heal on its own.[2] Once the disc has a weakened area or tear in the annulus, the disc is now vulnerable for further breakdown. Rather than this annular tear healing over time, as you might expect, the tear actually spreads through the disc and begins to break it down.[3] Once a tear in the disc is present some individuals can experience episodes of acute pain. This occurs when a portion of the nucleus slips into the tear and becomes entrapped within the rings of the annulus.



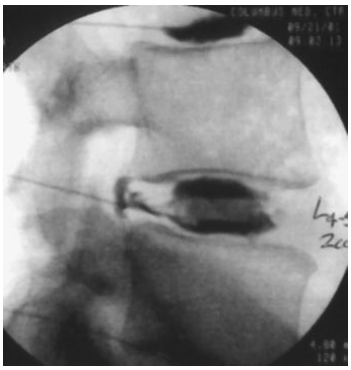
Here is a common scenario: an individual with no previous history of low back pain has ongoing degeneration of the disc with early degenerative changes in the annulus. This person now gets involved in a low speed rear-end car accident. As a result, a previously asymptomatic tear of the disc is now extended further into the annulus. Now the tear reaches the outer fibers of the annulus. When this occurs the person develops significant low back pain.

This causes a rather controversial problem. The person involved in the accident is now reporting low back pain. We cannot find anything wrong with the patient on more conventional diagnostic tests, such as MRI. The insurance companies do not understand why a 25 mph car accident could cause the ongoing pain the patient is describing. Worse, the patient starts going to health-care providers who are not trained and

equipped in making such a diagnosis, racking up medical bills for treatment that is completely ineffective. Bills are now mounting and the patient does not have any objective evidence of an abnormality.

Annular tears can extend all the way to the outer fibers of the disc, as seen in the picture above. The annular tears can also extend into the the innermost part of the disc. The proteins of the nucleus are foreign to other parts of the body. When they leak to the outside of the disc it often causes an autoimmune reaction and inflammation. There are also chemicals within the disc that can leak from the disc to surrounding tissues, specifically around the nerves, sensitizing them and causing pain.[4-6] The chemicals leaking from the annular tear of the disc can also cause congestion and inflammation of nerve roots and mimic sciatica, similar to what can be experienced with a herniated disc.[7]

The trouble is, if an MRI is obtained with this type of disc problem it may be read as normal. It may show some age-related degeneration of the disc, but this is also normal. So here you are, with low back pain, seeking care from physicians and they tell you that the CT scan was normal, X-rays are normal, and there is only mild degeneration of the discs on MRI, also normal. The patient is often told that there is no "objective evidence" to support their current complaints of back and peripheral leg pain. One can only imagine how devastating this must feel for a patient who may be desperately seeking help and a resolution to the problem.



There is a test called a “discogram,” shown to the right, that can be used when visual evidence of these tears is needed to confirm the diagnosis. This is discussed in detail in my article on discography, which you can also find on our website.

Do Doctors Understand the Annular Fissure?

Not only do most doctors not understand this condition of the lumbar spine, but some radiologists reading the MRI studies may not realize the importance of the annular fissure. There was an era in radiology in which most radiologists would ignore this finding all together. Today, most radiologists are very much aware of the manner in which these manifest on an MRI image and will usually discuss this finding in their report. The importance of such a finding will still need to be clinically coordinated with your problem. Unfortunately, just because such a finding is present on the MRI does not necessarily mean that it is a significant finding.

Some researchers have found that there is a high correlation between the finding of annular fissures on MRI and a confirmatory result with a test called a discogram, as discussed above.[8-10] Others are not so convinced of this correlation. We will cover the controversies of MRI and annular tears in a later section of this article. The truth of the matter is that whenever findings are identified on the MRI it must be accompanied by a detailed examination to corroborate those findings. There are, in fact, specific examination procedures that can be utilized to confirm MRI findings and help us determine whether an asymptomatic annular tear is present or not. We typically do not have to do discograms in order to sort this out. (This is further discussed in the aforementioned article on spinal discography.)

Many family physicians are unaware that such a condition exists in the lumbar spine and often diagnose a patient with an annular tear as having a “lumbosacral strain.” Because the annular tear can cause significant spasms and pain along the muscles of the lumbar spine it is often mistaken for a strain.

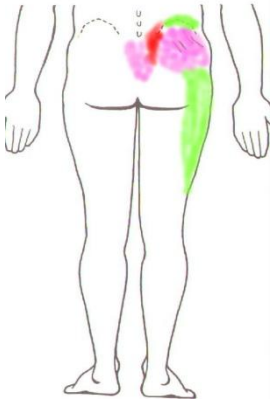
However, this could not be further from the truth. It is important to understand that the annulus of the disc causes much more muscle pain, and more spasms, than a muscle strain. If a physician is unaware of this condition they will misdiagnose the problem.

The annular tear or fissure is also one of the most misunderstood conditions among manipulative therapy practitioners, such as chiropractors and osteopaths. This is not universally true, but as a consumer of health-care services you will commonly encounter it. Because their focus is often primarily on joint dysfunction and the soft tissues around the spine, their perspective can be skewed to fit their "model" of back pain. Thus, they often miss this condition in their evaluation.

To add to the problem and the difficulty in making the diagnosis, these annular tears and fissures mimic many of the lesions that these practitioners often treat that *do* involve joint dysfunction. For example, the annular fissure will often mimic a problem in which the pain comes from the facet joints or may mimic chronic sacroiliac joint dysfunction. The practitioner may not realize the true source of the pain because their focus, training, and, unfortunately, even *beliefs* about what causes back pain may lead them to false conclusions.

On the other hand, manual therapists who are well-trained to recognize this condition will often be able to sort the diagnosis out more quickly than other specialists, even without the high-tech diagnostic tools that medical specialist have at their disposal. It is therefore important for you to understand the great disparity and differences amongst various health-care practitioners and their understanding of this condition.

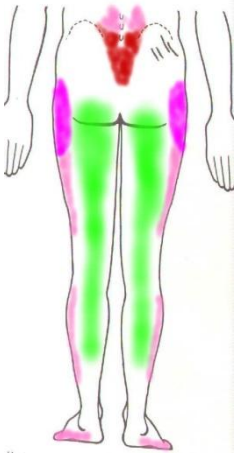
I have already alluded to this previously, but one of the difficulties with making a diagnosis amongst doctors is that the way in which the disc refers pain can mimic the pain patterns of other syndromes of the ligaments, muscles, and joints. For example, the L4-L5 annular tear radiates its pain directly over the sacroiliac joint and extends down the buttock to the posterolateral thigh, as seen in the diagram to the right. This will mimic sacroiliac joint pain; patients experience intense pain directly over the sacroiliac joint. Interestingly enough they will also be very tender to touch directly over the sacroiliac joint, further confounding the problem. Now you have pain and tenderness over a region where the pain is not even coming from. The picture to the right is a typical pain pattern referred from the L4-L5 disc. The region in red is the area where the pain is most intense.



This has taken me years of personal experience to sort out. I performed thousands of sacroiliac joint injections on patients who I thought were presenting with sacroiliac joint pain. After injecting local anesthetics into the joint I was surprised to discover that these patients did not experience any symptom relief. Perplexed by this, we then performed a discogram on these patients and found that all too often the pain was coming from a L4-L5 disc. When the discogram was performed it corroborated the specific complaint that the patient had overlying the sacroiliac joint.

In my early years of clinical practice I was not sure whether this was a fluke or whether I had stumbled onto a problem that I had been misdiagnosing for years. I have spoken to many physicians over the years that sub-specialize in advanced diagnostic procedures for spine pain patients and they have discovered the same thing. Today there are many specialty-trained physicians who are very much aware of this phenomenon. There are other conditions that mimic sacroiliac joint pain, but these will not be covered in this article. I coined the term "pseudo-sacroiliac syndrome" in the 1990s as I began to learn how to differentiate patients with disc pain simulating sacroiliac pain from those who truly had sacroiliac joint dysfunction.

Pain from annular tears in the disc can also masquerade as other low back pain syndromes. If the tear occurs at the L5-S1 disc the pain referral pattern is different than the L4-L5 disc. The pattern will also vary depending on where the tear is. The L5-S1 disc radiates its pain into the lower "small of the back" centrally, extending over the belt line. The pain from the L5-S1 disc can also refer pain directly over the center of the buttocks or sacrum and can look like just about everything that a manipulative therapist sees in practice, e.g., facet syndrome, sacroiliac syndrome, etc. Once again we have a disc tear that is masquerading as something else. The picture to the right demonstrates various pain patterns that can occur from the L5-S1 disc. Some patients may also experience pain overlying the outer hip joint. There are many things that can cause this; a disc tear is one of them.



So what happens to these patients? It depends on the health-care practitioner, their model of where they think the pain is coming from, and what type of services they provide. I hope you can see that you could spend a significant amount of time and money seeking care for something that is eluding the practitioner.

Annular fissures also occur in the cervical spine. This condition is not as common in the cervical spine as it is in the lumbar spine. Nevertheless, it can be a source of chronic neck pain. In the cervical spine it is often more difficult, even for the best of practitioners, to differentiate neck pain of disc origin from other sources (such as from the facet joints) by physical examination.

The annular fissure in the cervical disc is also a masquerader, disguising itself as many other clinical entities, confounding diagnosis and management. For example, it is common for the lower cervical discs to refer pain and tenderness to the region between the shoulder blades. These patients will have very tender muscles in the neck and across the shoulders, mimicking many myofascial syndromes. They will also experience tenderness between the shoulder blades and over the ribs in the mid back. I have seen patients undergo numerous trigger injections, physical therapy, and chiropractic treatment procedures for pain between the scapula only to later find out the pain was discogenic. Despite well-intended efforts, treatment providers who misdiagnose this condition can, at best, only provide a period of transient pain relief.

The patient depicted in the MRI to the right is someone I saw for chronic neck pain and upper thoracic (mid-back) pain. She had this pain for years and had failed most methods of conservative care. She was seeing a chiropractor once per day, sometimes twice a day, and would plan her day around her chiropractic visits in order to keep her symptoms under control. She had done this for *years*! Was the chiropractic treatment helping her? It was certainly her perception that it was. It was the only thing she had found to get her out of acute pain when she experienced a flair.

What do you think that small white area is on the MRI? It is a high intensity zone that indicates an annular fissure is present. This was later confirmed to be contributing to her chronic pain.

Sharing this story is getting ahead of myself, but I can tell you she had an excellent outcome once we determined the cause. You see, she had significant multilevel segmental instability in the cervical spine. It was not just an annuluar fissure that was at the heart of her particular problem, but a complex syndrome of multilevel instability, with all of its associated soft tissue pain syndromes. In this patient's case we utilized a technique of injections called "prolotherapy," (which is described in detail in another article on our web

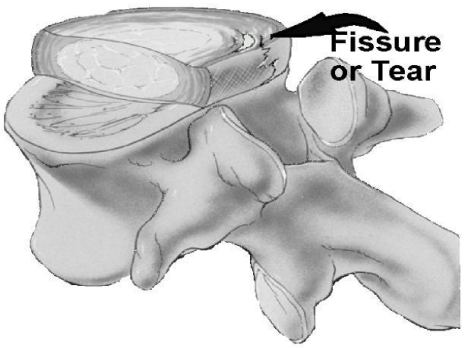
site.) Because she had too many levels of segmental pain we did not want to see her go through a multiple level fusion surgery. She, in fact, refused an offer for surgery. After about a dozen series of injections directed to the ligaments of the cervical and upper thoracic spine she has had almost a complete resolution of her pain. She now sees the chiropractor in her community only on rare occasions. I see her maybe once every two years for a booster injection and she has her life back. Her husband was most grateful as well.

This treatment did not address the annular fissure directly. In this particular case we approached a myriad of problems she was experiencing by stabilizing the cervical spine with these injections. This seemed to provide enough relief that we were able to avoid surgery. There are reasons why stabilizing the joints of the neck resulted in pain relief, but we will not go into that for the purposes of this article.

Unfortunately, annular fissures and disc pain can also occur in the thoracic spine. When they occur in the thoracic spine they mimic many other syndromes involving the cervical and lumbar discs. I can still to this day recall my first encounter with a patient who had an annular fissure or tear in the thoracic spine, or at least the first one that I recognized. She was the wife of a prominent attorney in our community and had been involved in a car accident. She developed significant mid back pain. Interestingly, the majority of her pain was not isolated to the thoracic spine, but rather extended to include the muscles overlying the ribs and muscles of the mid-back. She had failed to recover after a long course of physical therapy.

In my early ignorance I directed her through more comprehensive care. She failed to recover from everything we tried, including facet injections, PT, manipulation, medications, exercise, etc. Her x-rays were, of course, normal, as was her MRI. Just what was wrong with this individual? Was she just going on about pain for personal gain? After all, she was the wife of an attorney. Could her knowledge of the medical and legal system be allowing her to fool so many clinicians? I ordered a discogram on this patient and, as you may have guessed, she had a tear in the disc that was the source of her pain. Finding the source of the pain eventually lead us to utilize a much different treatment approach.

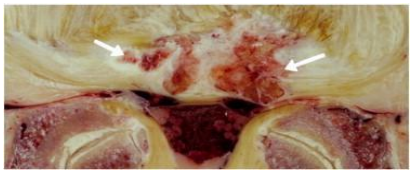
So now you know why I call the annular tear "the great masquerader." The annular tear and fissure can masquerade as a back pain strain, facet syndrome, sacroiliac syndrome, sciatica, herniated disc, and a number of other muscular and myofascial conditions that are common in musculoskeletal practice. Annular fissures can cause neck pain, mid-back pain, low back pain and can radiate pain into the arms or legs. An annular tear in one or two discs plus a few aches and pains from soft tissues such as ligaments and muscles can create diffuse pain that looks just like someone with fibromyalgia. Chiropractors and osteopaths that use manual therapy may diagnose these conditions only to be frustrated when treatment fails. A prescription of exercise and physical therapy may not provide significant symptomatic relief of pain either. Having the right diagnosis saves a lot of time and money and allows us to focus on the pathology before we intervene.



Do These Annular Tears Show Up on the MRI?

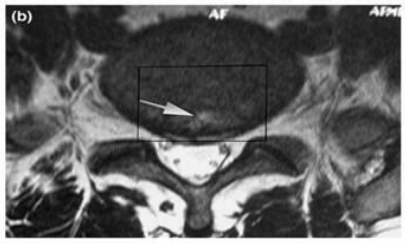
This is a very complicated question. I have already addressed the fact that annular tears can, in fact, be seen on MRI. This is a topic of both clinical interest and controversy. Before we go any further with this discussion, let us look at how a disc attempts to heal when an annular tear is present and just what an MRI is capable of picking up when performed on a patient with such a condition.

The disc has a very poor blood supply. Although the majority of the disc does not even have a blood supply, there are small capillaries that do supply the very outer portion of the annular rings. When the disc is torn the annular fissure can spread to the periphery of the disc, as shown in the picture on the right. The body will try to heal the tear, which it will do by forming a fibrous scar over the surface. In attempting to heal, small capillaries and blood vessels begin to form and migrate into the tear. This proliferation of blood vessels in the annulus of the disc causes the formation of small vascular "buds" that protrude into the tear of the disc. (This is shown in the picture below.)



Once there are small vascular buds pushing into the annulus, the MRI can pick up on these. In other words, the MRI does not detect the tear itself, but picks up on signs of the disc's attempt to heal. This phenomenon causes "white spots" or a signal on the MRI of what radiologists call a "high intensity zone," or annular fissure.

There is a special sequence of pictures taken on an MRI called a T2 weighted image. The technical aspects of MRI and that sequence are not important to our discussion. What is important is that this special MRI sequence is very sensitive to water or fluid density. Even the slightest fluid concentration change can be detected on the MRI. This is how we can visualize a small tear in the cartilage of the knee, for example. It is also how we visualize these tears in the annulus on MRI. Remember that a budding blood vessel has blood or fluid in the bud. This fluid will signal as a white color on these MRI sequences.



The annular tear or fissure is shown in an MRI (as can be seen on the top picture to the right) as a small white "blip" at the back of the disc. Take a close look at the disc the arrow is pointing to and at the disc above it. Notice the small white dot is not present in the disc above.

The white dot is that bud indicating an annular fissure. The disc above has no visible annular fissure. Notice also that the disc with the fissure is darker than the disc above it. It is darker because it has less water held within the disc. Basically it has become dehydrated due to the internal changes occurring from degenerative disc disease. As we have stated, once the fissure reaches the external annulus there is an attempt from the body to try to heal this. Small vascular buds begin to grow into the area in an attempt to try to heal this lesion, but the healing is usually incomplete. The MRI is sensitive to water concentrations and thus it will pick up these little vascular changes as a "high intensity zone" or HIZ (meaning a fissure is present).

There has been a great deal of controversy over the importance of discovering an annular fissure with an MRI. Lam and his colleagues looked at 92 discs with noted HIZ phenomena on MRI (remember, that indicates the existence of an annular fissure). They performed confirmatory testing on these patients and concluded that there was, in fact, a significant correlation between abnormal disc morphology and the HIZ

noted on the MRI. They went on to indicate that the nature of the HIZ remains unknown, but it may represent an area of secondary inflammation as a result of an annular tear. They concluded from this study that the lumbar disc HIZ observed on MRI in patients with low back pain is likely to represent painful internal disc disruption.[9]

One of the first articles that got my attention on this subject was by Aprill and Bogduk, both individuals whom I hold in high regard. They described an 86% incidence of concordantly painful discs in patients with low back pain that exhibited a high-intensity zone on MRI. They assert that the high-intensity zone is a reliable marker of discogenic pain in symptomatic subjects. They also found this to occur in 28% of 500 low back patients undergoing MRI.[8]

Shortly after Professor Bogduk published his findings on the subject, another group of researchers repeated this study to see if they could corroborate these findings. This was done by Saifuddin, Braithwaite, and colleagues. They found that the high intensity zone on MRI correlated 87% of the time in patients with symptomatic low back pain. As such, they concurred that the high-intensity zone is a reliable marker of painful outer annular disruption. In the early years of MRI, I too looked very closely at this finding and found it correlated relatively well in our clinical practice.

Many researchers, however, were not convinced. Rankine et al. noted only a 45% correlation.[13] They indicated that the presence of a high-intensity zone does not define a group of patients with particular clinical features.[13] They were not alone. Ito and his colleagues also indicated the presence of these tears were not a reliable predictor of a painful disc on discography. They concluded that, although the lumbar intervertebral discs with posterior combined annular tears are likely to produce pain, the validity of these signs for predicting discogenic lumbar pain is limited. They did note that the HIZ on MRI is a relatively reliable predictor of pain, but they related that the statistical values were lower than those in previous studies.[14]

An MRI of the disc loses its signal intensity as the disc degenerates. On the T2 image previously discussed the degenerated disc gets darker. As the disc gets darker on the MRI one may also see a decrease in the disc height as the disc becomes further degenerated and breaks down internally. The loss of intervertebral height and/or abnormal signal intensity on magnetic resonance imaging has been shown to be associated with disc disruptions extending into or beyond the outer annulus on discograms. One can differentiate lumbar disc protrusions, disc bulges, and discs with normal contour but abnormal signal intensity.[15] Other researchers have also noted that the more degenerated a disc is the more likely it is to be responsible for pain. However, no abnormal lumbar disc signal pattern could be identified that specifically indicated whether a disc would be painful. They concluded that discography is still the only method for symptomatic assessment in low-back pain.[16]

What I am saying is that one cannot rely completely on an MRI to make a determination as to where your pain is coming from. This is very important to realize. The other significant point I want to make is that a patient can have no visualized evidence of an abnormality on MRI and still have a symptomatic tear in the disc. We will address this issue further when we discuss the use of discography.

The next time you, a friend, or a loved one are sitting in a physician's office and the physician comes in and reports "your MRI is normal; there is not a thing wrong with you," you may be in the wrong place. Just the opposite can also occur. You can have a doctor try to diagnose all of a patient's problems based on a dehydrated and bulging disc on MRI. This may be equally inappropriate under certain circumstances. Let me repeat my message here: you cannot rely on an MRI as the sole method of determining where the source of you pain is! The MRI is just one piece of the whole diagnostic puzzle.

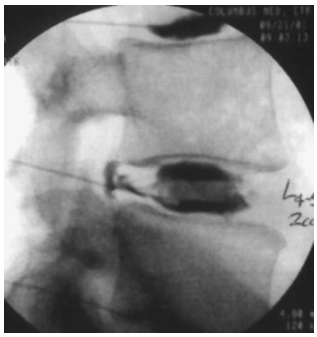
How is the Annular Fissure or Tear Diagnosed?

Making the diagnosis of a painful annular fissure is done by some sophisticated medical detective work. The diagnosis of the annular fissure is done both clinically and by combining sophisticated imaging techniques for confirmation. The clinical suspicion that an annular tear is present is reached by combining a thorough history of the problem and a detailed look at the way in which certain activities, movements, and postural positioning affects your pain. It is also helpful to do a careful, repeated assessment of your pain response to specific movements of your spine carried out to the end of your range of motion. A well-seasoned clinician who is experienced in evaluating discogenic pain patients can usually predict what will be seen on the MRI and discogram just by doing a thorough history and performing a comprehensive examination. In fact, it has been shown that a well-trained clinician can predict discography findings with uncanny accuracy.[19] This specialized technique of examination was made popular in New Zealand by physical therapist Robin McKenzie.[20] We call this method of examination the "McKenzie Exam" after him.

I have made my own modifications to this technique over the years, and it has become one of my foundational examination procedures. I use it in conjunction with other physical examination techniques and MRI review to evaluate patients with possible discogenic back pain. If a health-care provider is trained to clinically evaluate a patient in this manner, not only will the provider be able to tell you whether or not you have an annular tear, but he or she may be able to tell you the extent, size, and position of the defect or tear in the disc based on the physical exam.[21] Unfortunately, most physicians are not trained in how to use this system for evaluation of patients with back pain.

The MRI is only a tool in the process of making a diagnosis. It should be used as a helpful supplement rather than as the sole diagnostic tool in determining whether there is a problem with your back. You will commonly read in radiology reports that some of your discs are "desiccated." As a disc undergoes degeneration it loses the ability to hold as much water. It becomes dryer and therefore looks darker on a specific MRI sequence. This loss of water, or dehydration, within the disc is called dessication.

Remember that it is entirely possible that the MRI might not explain the cause of your pain. Just because there is a disc bulge, a desiccated disc, or disc degeneration, this does not necessarily mean that this specific level of your spine is the source of your pain. I cannot tell you how many people begin telling me their history with things like "I have three bulging discs, etc. etc." People wear these diagnoses like badges of honor. They cling to the diagnosis made by the MRI when really it means nothing!



Medical providers are also known to misuse MRI findings. It is not uncommon to have a patient tell me that they consulted a medical specialist who simply looked at their MRI and said, "There is absolutely nothing wrong with your back." What they *should* say is that the MRI does not explain the cause of your pain. Of course there may be the occasional person who is using a simple bulge or MRI finding to fake a condition or injury for personal gain. This is rare, but is an unfortunate reality in our society; I have seen it myself on a number of occasions. Nonetheless, we have our ways of sorting that out as well.

So, if the MRI is not the gold standard for disc pain diagnosis, what is? There is a technique called 'provocation on discography' that is occasionally used to make the diagnosis of discogenic pain or a painful annular tear. This technique is not without its controversies as well. I will not address these in the context of this article, but if you are interested I would encourage you to read my article on discography.

Basically, a patient who undergoes discography goes into a surgical fluoroscopy suite, a needle or catheter is inserted into the disc, and a contrast solution is injected. This process stimulates pain that can replicate your typical symptoms and also is a means to visualize the tear or defect in your disc.

I prefer to use discography sparingly and there are many reasons for that. I believe that one can sort out whether or not someone has pain from the disc many other ways without resorting to such an invasive procedure. If the physical assessment using a modified McKenzie examination is not able to make the diagnosis then one can use fluoroscopy controlled diagnostic blocks to rule out other causes of pain.

A fluoroscopy unit is a specialized x-ray machine (shown to the right). It can be used by a trained medical specialist to do precision, guided diagnostic and therapeutic injections. By using these diagnostic blocks one can help sort out the causes of spine pain, which can help us make a much more accurate diagnosis in determining the source of the pain. Only rarely do we have to use discography.

I feel strongly that the use of discography is important as a diagnostic tool, but only when one cannot find the source of the pain by other methods. Although the discogram has been considered the gold standard in making the diagnosis of painful annular tear, typically we can sort this out by using the less-invasive methods previously described.

The Vibration Sensitivity Test - A low-tech method of determining internal disc pain

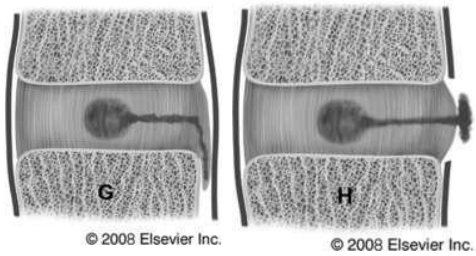
A number of spine specialist and surgeons carry a rather simple tool around with them in order to test for the presence of painful lumbar discs. What tool is this, you ask? It is none other than a simple vibrator. When applied to the spine at each level of the vertebra, this tool's strong vibration stimulates discogenic pain. Several studies have found a correlation between this pain and positive findings noted on discography. This is just one more simple tool to be used alongside other physical examination techniques and detailed history-taking to help us determine if there is a painful lumbar disc.[21]

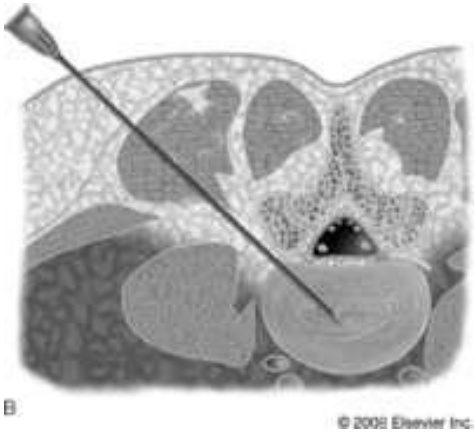
Disc Derangement vs. Annular Tear

In a previous article we described a phenomenon called 'the internal disc derangement.' To explain briefly, a disc derangement occurs when a portion of nuclear material moves into a weakened area or tear in the disc and the nuclear material becomes entrapped, causing severe back pain. This often results in a tilted (antalgic) posture. The entrapment is usually reducible and can be moved out of this defect, thereby relieving some, if not all, of an individual's pain. Some patients who experience such an episode can remain completely asymptomatic for months, or even years, between episodes. A patient with an internal disc derangement may or may not have a positive discogram. This is one very important difference between the annular tear patient and the internal disc derangement patient.

In the case of an annular tear or fissure, the tear can extend into the periphery of the disc (as seen in the picture to the right). This can then leak noxious substances that cause inflammation and pain around the

nerves (also shown to the right). Remember the outer fibers of the annulus are very pain sensitive. In this situation, if one were to inject a contrast material under pressure in the disc, the injected solution would travel right through the tear and exert pressure on the outer fibers of the annulus, or leak out of the tear when the test is performed. This can stimulate the patient's usual pain and is precisely what is done in discography.





Remember that a derangement is often the beginning of a disc disease cascade. Many patients with a history of periodic derangements can eventually progress to a tear. An individual may have no history of derangement and experience a tear with a lifting incident or injury. Many annular tear patients may not experience the same locking sensations that the derangement patient has and typically is not noted to have the "antalgic" posture that is so common in the derangement patient.

A patient may also have both. They may have an annular tear that causes a dull, constant pain that increases with activity. They could also experience periodic, acute episodes of pain, with associated antalgic posture, when a portion of the nucleus shifts within the disc and becomes trapped in the tear. Technically speaking, a patient who has periodic acute pain from a disc derangement has an annular tear or fissure. But the tear is often in the internal sections of the annular rings and thus may not have continuous pain like the annular fissure patient.

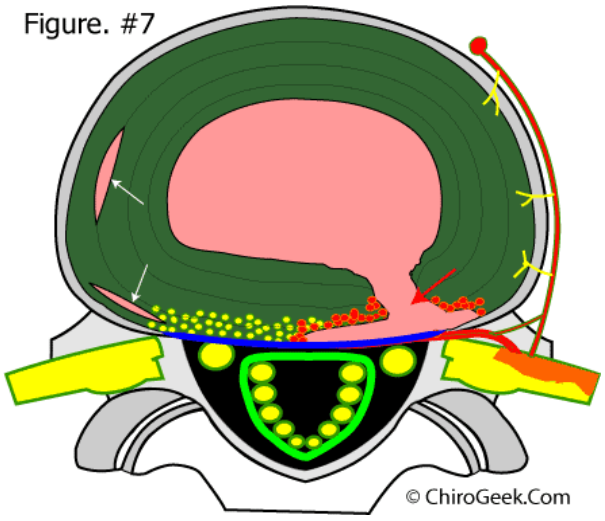
One might think that once the disc becomes dehydrated with extensive degeneration that there would be no way a patient could have episodes of acute pain and shifted posture from an internal disc derangement. However, this is not the case. I have seen many patients with significant degenerative disc disease who still have these derangement episodes. How could this be?

Even in discs that have undergone significant degeneration and dehydration there can still be left-over fragments of hydrated nucleus in the middle with the ability to move around. If this piece of viable nucleus shifts along the fissures of the disc it can get trapped, causing acute pain. There are other times disc dehydration and degeneration are your friends! You could have a history of these derangements and, over the years, as the disc dehydrates it stiffens. When this occurs the nucleus is no longer mobile within the disc and will not shift positions. Once this occurs, you may have very few problems with your back from that point on!

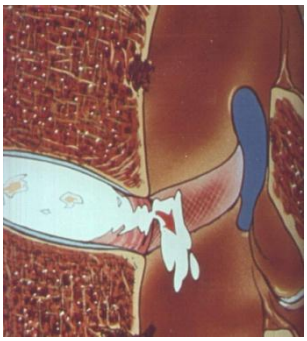
I have discussed this theory with my colleagues for years, many of whom doubted this could happen. Once they started using the new fiber optic scopes and laser procedures they too discovered these viable fragments of nucleus within a degenerated disc, exactly as described. Laser ablation of the fragment resolved the patients' pain! Remember, this is not the case with everyone, and it takes a physician acting as a medical detective to sort it out.

Types of Annular Tears and Fissures

There are a number of different types of annular disruptions or tears. The tear can begin on the outside and work its way to the center of the disc. The tear can also occur in a circumferential fashion better known as a "rim tear." The rim tear represents a separation of the annular rings along the outer portion of the disc, shown in the figure to the right at the red arrow. There was a time when we did not think that these types of tears actually caused significant pain. As we have improved our discogram techniques we have found that these rim tears can cause pain. With some rim tears both the MRI and the standard discogram may appear normal! This lesion may not show up as the source of pain unless one does an annulogram rather than a discogram. (Please review the discogram article for more information.)



Another type of tear occurs when the annular fibers begin to tear from the inside of the disc near the nucleus and then progresses out to the periphery of the disc. There are two types, or sets, of rings in the annulus. The inner set of rings is more cartilage-like. These inner cartilaginous rings are responsible for containing the nucleus and withstanding significant compression loads applied to the disc. The outer set of rings of the disc is more fibrous in nature. These rings are set up in layers like the plies of a “radial tire.” It is these fibrous rings that are quite pain-sensitive, as they have a rich nerve supply.



Most tears in the disc begin with a break in the cartilaginous inner annulus. Then the nucleus begins to make its way through the tear. This tear will then open and spread into the outer annulus, eventually extending to the outside of the disc. As we have already stated, in the presence of a full tear to the periphery or outside rings, the disc can leak substances outside the disc that are powerful inflammatory chemicals. These chemicals around the nerve and other structures in the spinal canal cause inflammation and pain. This is very important to note. It is the reason so many people can be benefited by epidural steroid injections. The tissues exposed to the effects of these chemicals become quite sensitized to pain. Even structures that are not usually that pain-sensitive will become mechanically sensitive. Sometimes, because of the chronic exposure of the spinal tissues, particularly those tissues within the spinal canal, a thickening of tissue along the inside of the spinal canal can form what is called an "inflammatory membrane."

It was the surgeons specializing in endoscopic spinal surgery that first began to notice these inflamed tissues and membranes and to find just how pain-sensitive they had become.[24] To visualize these membranes, a fiber optic scope is inserted into the neuroforamen to provide a view of the tissues surrounding the nerve roots and the tissues just behind the disc. These tissues are much harder to observe in an open spinal surgery because of the bleeding, etc. This inflammatory membrane has been thought to be another possible, hidden source of chronic pain. If it is not recognized at the time of treatment, teased gently away and ablated many times, the pain continues despite the heroic efforts of the doctor trying to help you.[25]

A spinal surgeon who has specialized in endoscopic surgery of the spine can remove this inflammatory membrane, thereby assisting recovery. This is a tricky business and the techniques are, unfortunately, only known to a few. That is changing, however. There has been a significant increase in the number of surgeons being trained in these methods over the last 10 years.

Treatment for Annular Tear or Fissure

This is one of the most puzzling questions for doctors who treat spine pain patients. What can we do for disc pain caused by an annular tear or fissure? There are no easy answers to this question. The treatment of discogenic back pain and annular tears is possibly one of the most controversial topics in interventional spine practice today. Careful patient selection and evaluation of individual variability are vital, as this requires an extremely complex clinical decision-making process. The topic of treatment for discogenic back pain will be covered in multiple articles on this website.

The first thing we must acknowledge is that one cannot discuss discogenic back pain without addressing the importance of conservative rehabilitation treatment. Over the years, with my manual and rehabilitation medicine background, I have implemented countless rehabilitation strategies, including various exercise protocols, corrective movements, high-tech rehabilitation using computer-assisted exercise machines, as well as low-tech exercise technology. We have used spine stabilization techniques with gym balls, foam rollers, rocker boards, resistance bands, etc. We have utilized McKenzie exercise strategies and categorization procedures all with, of course, some success.

It is critical to develop a strategy of core stabilization and strengthening as a foundational approach to the care of all patients with discogenic back pain. I recommend that anyone with discogenic back pain read my article on spine stabilization for information about how to participate in exercise without aggravating the condition. Suffice it to say, anyone with back pain can be put through a protocol to increase strength and endurance without aggravating the condition. It takes training and very special techniques to accomplish this, implemented and customized for each individual.

During my early years in clinical practice I fell into the trap of recommending spinal fusion surgeries to patients with discogenic back pain. After seeing countless treatment failures I began a 26 year journey traveling around the world looking for technological answers to the treatment of discogenic back pain. It led to my participation in multiple fellowship training programs. It also led me to leave my clinical practice in manual medicine and go back to school a number of times, eventually leading me to medical school, an internship, a residency, and not one but two interventional spine fellowship programs. Although I do not have all the answers to this complex question I have expanded the scope of my capabilities, taking advantage of technologies as they arise and participating in important clinical research to develop new technologies for patients with discogenic pain.

I was fortunate to have practiced with David Salinger, M.D. in Los Gatos, California--one of the first interventional spine practitioners in the US--to begin utilizing radiofrequency nucleoplasty and radiofrequency annuloplasty. After having visited a physician in the Netherlands who came up with the idea, Dr. Salinger was the first person (that I know of) to understand how to systematically use this technology for the treatment of annular tears. We did this for years and it eventually sparked interest among other spine specialist around the world.

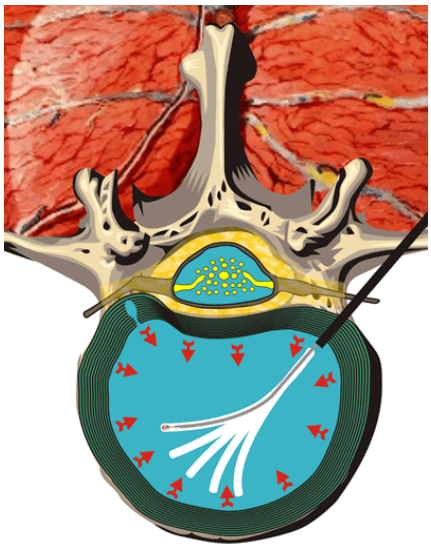
In the early 1990s we introduced a technique whereby a radiofrequency probe was inserted under fluoroscopy into the nucleus, and thermal energy was utilized to coagulate the nucleus and alter its mechanical behavior. In addition, we would place the probe near the periphery of the disc where thermal energy from the radiofrequency probe would coagulate the proteins of the annulus fibrosus. This would shrink them and, theoretically, seal or alter the mechanical behavior at the tear in the disc. We described this technique in 1997 in a newsletter of the International Spinal Injection Society.[26]

We enjoyed significant success with this technology. Having a personal interest in physical assessment, categorization procedures, biomechanics, and manual medicine, I quickly began to realize that we could utilize specific criteria to better select patients for these procedures. It was Dr. Salinger's original work in this area that was the start of all of the intradiscal technologies that have proliferated over the course of the last 20 years. The radiofrequency that we used in the early 1990s was a basic modification of radiofrequency techniques that have been around for years. We just modified the probes.

Radiofrequency had previously been used to denervate the nerves from the facet joints. The details of that procedure are discussed in another article. We simply began inserting the radiofrequency probe into the disc. The radiofrequency probe works much like a microwave, resulting in a thermal effect. Like a microwave, the more water is contained within a structure the more efficient the thermal effect. We began to learn very quickly that the dryer, more desiccated and degenerate the disc was, the less efficient radiofrequency was in treatment. Many patients with substantial disruptions within the disc (internal disc disruption) may have significant symptomatic relief when treating the annulus and thermally shrinking it to affect the mechanical behavior of the disc. Unfortunately, with advanced degenerative changes, many times the results were not long-lasting and symptoms could return within a few years.

Early pioneers in the Netherlands used to insert the radiofrequency probe into the disc in an attempt to thermally heat the entire disc and annulus. This was because they felt there may be a denervation or a "killing" of the nerves in the disc. Later this was found not to be the case at all.[27] In fact, there is no destruction of the nerves around the periphery of the disc that occurs, no matter where you place it in the disc. In the early years of utilizing this technology we began to realize that the thermal lesioning was affecting collagen protein, coagulating these proteins and causing a shrinking effect.[26] This collagen protein shrinking was secondary to a denaturing effect on the proteins, similar to the effect heat has when frying an egg white. What was occurring was a cauterization or a burning of the disc that was stimulating a shrinking of tissues at the site of the annular tear.

They discovered that this worked much better if the probes were introduced close to the internal tear of the disc or at least as near the tear zone as possible. It was at this location that the radiofrequency stimulation or heating stimulation could have a more direct effect on the weakest part of the disc. This resulted in a new modality of treatment that showed great promise for the annular tear or fissure patient.



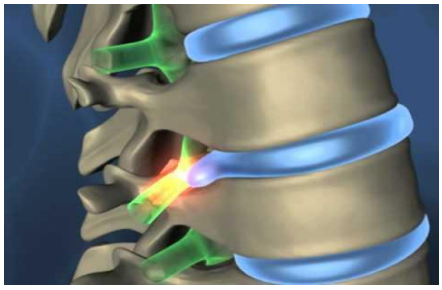
This was to be only the beginning, and soon two other technologies were introduced. The first was IDET, which I will describe later. The second was Coblation nucleoplasty, introduced by ArthroCare.

ArthroCare began in California very near our facility. They contacted Dr. Salinger (whom I worked for at the time) to assist them in their early development of techniques utilizing this new technology. They introduced a means of vaporizing tissue, utilizing

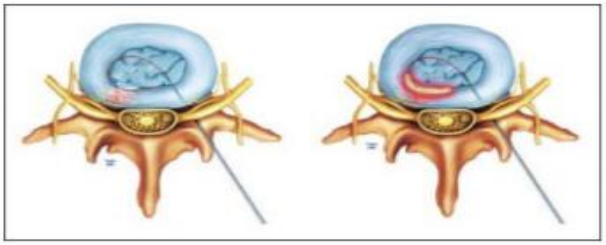
radiofrequency energy at the tip of the needle. The needle probe is introduced into the disc, as shown in the picture to the right. It is then flushed through the disc with several passes. Each pass ablates or vaporizes a track within the nucleus, removing the nucleus as the needle probe is pushed through the disc. During withdrawal, a radiofrequency thermal energy is applied to cause a shrinking effect. With several passes of ablation, followed by coagulation, the theory was that you could remove a portion of the nucleus and reduce the pressure within the disc, thereby altering discogenic pain.

We were the first to conduct a clinical trial using this technique, and we presented our results at a conference in San Francisco. I expressed my concern at the time that we did not know what effect this technology had on the internal disc and its movement dynamics. We did have preliminary success. It is my personal opinion that, although this technology is unique, it is not a technology that is helpful to most patients with discogenic back pain. Later, one of my mentors and colleagues at the University of Washington did coblation studies on fresh cadaver discs only to find that the internal disc was being fragmented by this technique.

In 2009 one of my colleagues and mentors published a systematic review of this technology.[28] Their conclusion was that there may be some evidence for its use with patients who have leg pain from a disc bulge, but there was no evidence that it was effective for treating back pain. This was my conclusion as well.



Percutaneous lasers have also been utilized for both treatment of back pain caused by annular tears as well as the leg pain caused by contained disc protrusions.[29] Percutaneous laser technology does offer some benefit to patients fitting specific criteria. The remaining question with this technology is whether or not patients can benefit long-term and not just for 2-3 years. Typically this technology is used for the aforementioned contained disc protrusions.

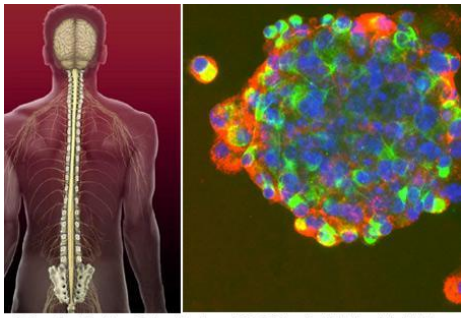


Another technique that is commonly used in Europe, but rarely used in the US, is the utilization of oxygen ozone injection in the intervertebral disc. This technique is so unique and so interesting that I will devote an entire article to the subject for comprehensive review. To be brief, normal molecular oxygen (or O2) has a stable bond between its two oxygen atoms. Ozone is generated when a single oxygen atom (1 O) bonds with an O2 (molecular oxygen) to become O3, ozone. This is a very unstable chemical state. When O3 is injected into the disc, an oxygen atom is released and immediately wants to bond to become stable. It oxidizes the nucleus pulposus proteins, causing them to shrink. I personally use this technique and find it to be very promising. It is also one of the safer intradiscal procedures that we can utilize today. Patients must fit specific criteria, but this technique offers great promise.

There have been many modifications to thermal lesioning of the annulus initially done by radiofrequency. as we previously described. Years ago, another group of physicians working in Los Gatos, California developed intradiscal electrothermal annuloplasty (IDET). Instead of using radiofrequency thermal coagulation of the annulus of the disc they used electrothermal energy. In this procedure a probe was placed within the disc and a circular coil is extended through it, coiling back around the tear in the disc. Electrothermal energy is used to coagulate the disc and seal the tear or alter the mechanical

behavior of the disc. We performed 100 of these in the 90s and found that initially patients did quite a bit better, but within a year after the procedure most patients' pain returned. We eventually discontinued using this procedure.

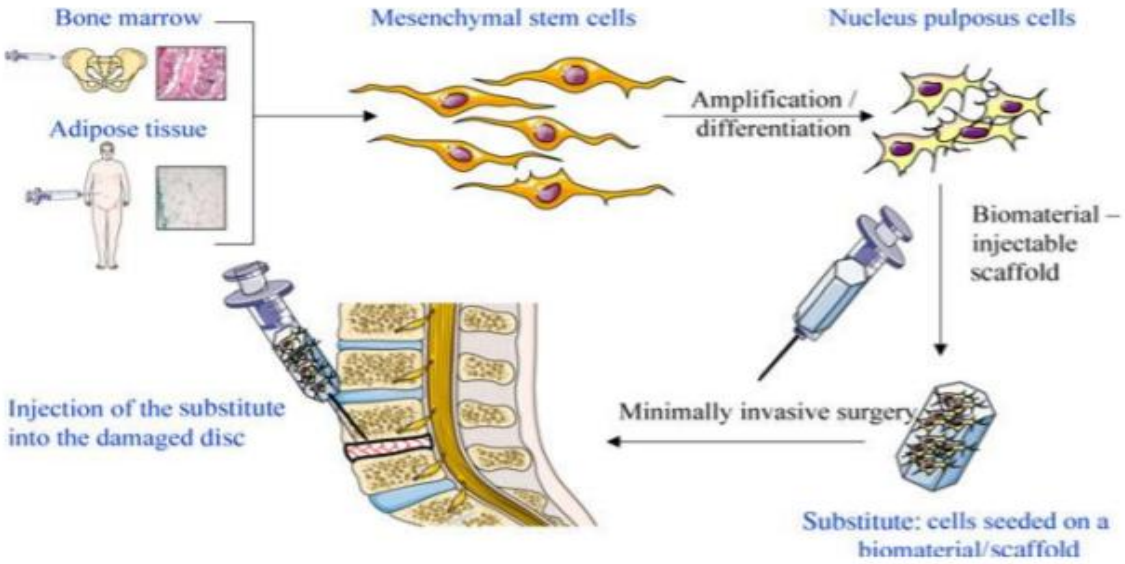
Other minimally invasive spine specialist have tried placing probes into the disc and taking some of the nucleus out of its center, thereby decreasing the internal disc pressure. This is done by a small microscopic agar bit, as shown in the magnified picture to the right. This has met with some success, but it does not work on all patients with disc pain and has thus fallen out of favor over the years.



Stem Cell Therapy for Disc Degeneration, Disc Pain, and Annular Tears

The use of cellular-based therapies for intervertebral disc pain has been a focus of our facility for years. We have explored numerous protocols and techniques, including the use of intradiscal PRP injection, platelet growth factors, proteins and sealants, and eventually stem cells. In 1993, convinced that the future of treating degenerative disc disease and disc pain was in cellular or biological treatment, we began doing animal research to develop a biologic treatment for the disc. In our research we used platelet-derived growth factors and platelet concentrations injected into the intervertebral discs of goats. A medical pathologist with a background in platelet physiology and a veterinary institute were willing to join forces with us to work on this research.

We began to work on thrombin and fibrin glue in combination with platelet concentrates at that time. Back then, platelet concentrations in plasma did not carry the name “platelet-rich plasma” as it does today. Much to my dismay, the project was canceled because of the actions of our pathologist. I have remained convinced that we were on the right track ever since. Twenty years later it turns out that I was probably right. I believe the future of treatment for degenerative disc disease and discogenic back pain lies in biologic and stem cell therapies.



A number of years ago publications began to report good outcomes from this procedure and we began injecting PRP (platelet-rich plasma) into the discs of patients. Although we have seen benefits from this procedure in select patients, the response to intradiscal PRP injection has been inconsistent. We then began to explore the use of two different stem cell techniques. As I have described on this website in other articles, we have used bone marrow-derived cells and adipose tissue-derived cells as part of our orthopedic treatment paradigm. Although typically I like to remain at the forefront of such treatments, this time I held back for a number of years, waiting for clinical outcomes and further results from my colleagues utilizing this technology. Several of the physicians in our network have been utilizing this technique for years. While they were collecting clinical outcomes, research began being published for both animal and human models on the effect that bone marrow-derived stem cells and adipose tissue-derived stem cells had on the intervertebral disc. We are currently writing a detailed article on the topic of stem cell therapies for degenerative disc disease, and when that project is complete the article will be posted on the website.

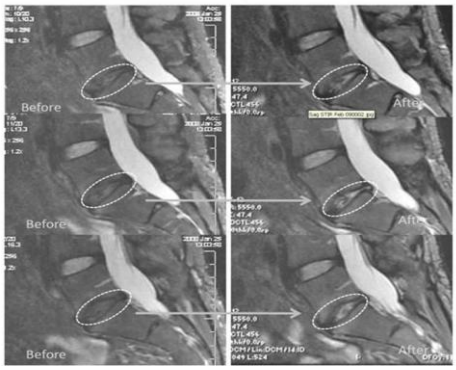
The number of studies published and currently underway utilizing stem cell therapy for degenerative disc disease is becoming robust. This includes the work of Pettine et al., who evaluated percutaneous injection of autologous bone marrow concentrate cells in lumbar discs for degenerative disc disease. They noted that there was evidence for the safety and feasibility of nonsurgical treatment of degenerative disc disease with these injections.[30]

Bone marrow-derived stem cell injections have also shown to reverse the dehydration and dark signal on T2 MRI, suggesting a regeneration of the nucleus of the disc.[31] Stem cell and regenerative procedures for the intravertebral disc have begun to gain a lot of momentum worldwide.[30-45] Organizations in the US have begun to heavily utilize bone marrow-derived mesenchymal stem cell injections for intravertebral disc disease and they have validated findings of rehydration and regeneration of degenerated discs, as noted in the images to the right. Other researchers have also documented the restoration of T2 signal intensity on MRI, which is typically improved after the injection of stem cells and a hyaluronic acid hydrogel.[46]

KG-39 yo WF-Pre-op Jan 08 Sag STIR 3.0T MRI with ET=12, TR=5550.0, TE=47.7

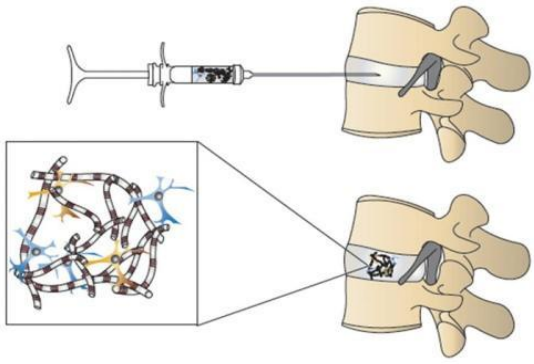
Post-op Feb 09 Sag STIR on same magnet with ET=12, TR=5550.0, TE=47.4

Note bright signal in nucleus pulposis of L5-S1 disc now more closely matches that of bright L4-L5 disc.

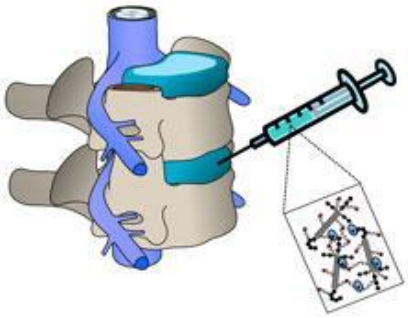


Several physicians in our organization have been performing bone marrow-derived mesenchymal stem cell injections. They've performed these on hundreds of patients, and the response has been so promising that the rest of us have taken up using this technique for the past two years. We then began to utilize other proteins extracted from patients' blood to help seal tears in the disc. Eventually we moved into adipose tissue-derived mesenchymal stem cell injections for the intervertebral disc.

It has been the latter that has shown the most promise. Adipose-derived tissue mesenchymal stem cell intradiscal injections seem to be demonstrating the same powerful anti-inflammatory and immune modulation effects as when used in other joints.



In addition to stem cell therapies, there is currently a great deal of work being done with other biologic therapies, scaffolding, and other substances that stimulate repair and regeneration. Some of these substances are currently



available on the market, made from embryonic membranes, etc. Several of my colleagues have been utilizing the combination of these substances and other regenerative and stem cell preparations within the intravertebral disc with excellent outcomes. We believe that in these "cell matrix substances" in combination with stem cell injections will probably be the wave of the future. Some of these therapeutic interventions are available at the present time. Others are currently in development and have not yet been approved. But that is changing rapidly.

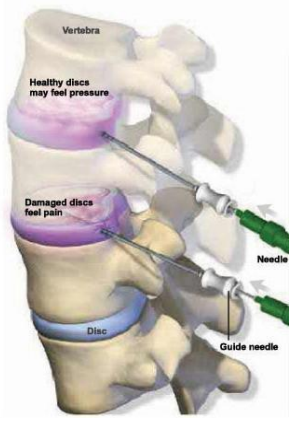
Not everyone is a good candidate for stem cell injection of the intravertebral disc. Careful patient selection is a critical component, and there is a great deal that needs to be taken into account when choosing a specific therapy for degenerative disc disease, concomitant nerve root compression, disc bulge, bony hypertrophic changes that lead to spinal stenosis, etc. Unfortunately, a properly multifaceted consideration of these factors and options has often been neglected, especially in the application of specific treatments for discogenic back pain.

What Are The Risks?

Discussing the potential risks of interventional procedures directed towards the disc is a complicated matter in itself. There are some universal precautions and complications involved in any interventional procedure involving needles or small probes placed in or around the disc.

First of all, if conscious sedation is utilized, there is risk of respiratory failure and reactions to medications used. Most pain physicians do not tell patients this, but for many interventional procedures the risks associated with conscious sedation are the greatest of those involved. It is extremely rare, but respiratory failure and accidental death are possible.

Other universal risks involve the potential of nerve injury, spinal cord injury, discitis (infection within the disc), and abscess formation (this can even occur in the epidural space, which can cause further neurologic damage). This is why we have adopted a protocol of injecting antibiotics into the disc, and through IV, in patients who are undergoing intradiscal injection procedures. This provides a substantial reduction in the potential risk of infection, and is based on the work of Dr. Derby, one of my mentors.

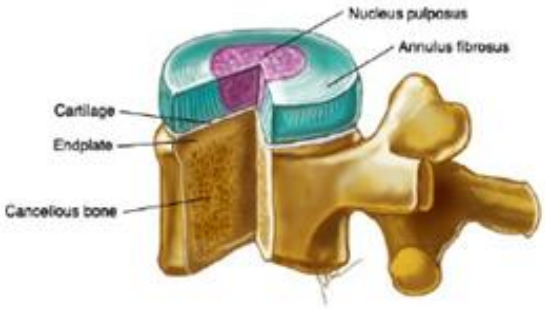


Undergoing such a procedure, especially within the disc, can make pain worse. Even the process of performing a discogram for the diagnosis of disc disease can make the condition worse. Our practice has adopted numerous changes to our procedures in an attempt to reduce these risks, but patients must be aware that they *are* still present. (For more information see our article on analgesic discography.)

Some patients can be allergic to the contrast agent used in discography or during intervertebral disc procedures. There is also the possibility of accelerated disc degeneration, depending on the size of the catheter or probe placed in the disc during the procedure. Simply placing a needle in the disc can cause disc injury in itself. We therefore keep our needle size limited to 25-

gauge.

In 1997 a physician/surgeon by the name of Carragee was doing research on discography. This procedure helps determine if a specific disc is symptomatic and allows a physician to properly categorize the type of disc disease that is present. However, it is not without risk. Carragee and his colleagues followed patients who had undergone discography for a period of 7-10 years.[47] He reevaluated these patients at that time with MRI and noted that, on the side and site where a larger gauge discography needle had been inserted into the disc, there was a higher incidence of disc bulge and overall higher incidence of disc degeneration in that segment. This research study altered the behavior of many pain and interventional spine physicians around the world. We have made many adaptations to our practice and disc procedures based on these findings.



As it pertains to procedures involving radiofrequency, thermal ablation, etc., these procedures do accelerate degenerative disc disease. The hope is obviously to improve chronic pain, but there is a price. The larger the probe or the larger the needle placed in the disc, the more damage occurs.

But risks involving intervertebral disc regeneration procedures are somewhat more complex. There is an old saying: today's answer is tomorrow's problem. Not only are there questions about what are the safest and most efficacious procedures for disc regeneration, there is also the question of whether we should use regenerative procedures at all and, if so, when and what type are appropriate for specific disc conditions.

Let me give you the perfect example: a colleague of mine who is an expert in intradiscal procedures and orthopedic spine regenerative medicine was consulting a woman with degenerative disc disease and a disc bulge. The disc was confirmed to be the source of pain and a stem cell injection was performed within the disc. Her back pain progressively improved, but she began to experience more leg pain. With persistent increased leg pain, a repeat MRI was performed. The MRI demonstrated reversal of the dehydration and degeneration of the disc! However, now that the disc was rehydrated, it was more hydro-dynamic and the motion of the nucleus of the disc increased. With the new hydrodialate, dynamic disc her disc bulge is actually bigger, and she now must go through a second procedure to reduce the disc bulge.

Although this is an unusual problem it does make the point and demonstrates how complex these problem can be. Patients undergoing platelet-rich plasma injection into the disc also often experience significant flare-ups of pain, which can last for weeks and sometimes several months. Although individuals can get better, and often do, in the long run there have been countless times when we have not proceeded with platelet-rich plasma injections because we knew the individual was not psychologically capable of tolerating increased pain for a period of, possibly, several months.

This is a relatively new field and we simply do not know all of the potential risks and side effects of disc regeneration. It has taken several years for us to even begin to understand what methods are most effective and when we should be using them. I have personally been fortunate to have a team of physicians and specialists to work with who had been meeting to compare methods and outcome data for some time. It is only through this shared experience that we have all improved our methods.

So, if you do not think that it is possible that you could be in any worse condition, you might want to think again. A complication or side effect from an interventional procedure directed to the lumbar, thoracic, or cervical disc can make the condition better or make it worse. This is a possibility you must be aware of.

CONCLUSION

There are no easy answers in annular fissure and discogenic pain treatment. Patient selection for any given procedure is critical. It is incredibly important to properly categorize the patient so that specific treatment algorithms can be established. This requires an understanding of the patient's history, biomechanics, and pathology, as well as an interpretation of the patient's diagnostic imaging. It also requires confirmation of the specific pain generators, often using diagnostic blocks.

After years of experience with multiple intradiscal procedures I can also say that there must be some consideration of cost, efficacy, and length of treatment time. Procedures that we did many years ago, such as IDET, seemed to be a reasonable alternative at the time. Although we did gain significant improvement in many patients, the results were not long-lasting, and within a year symptoms had recurred. Later, we abandoned the practice of using many ablative technologies within the disc and began searching for a regenerative approach.

We have worked very hard to find a means to keep the cost of intervertebral disc interventions reasonable to allow individuals to gain access to this technology. There are a number of institutions and providers that have made significant contributions to our methodology and understanding of intervertebral disc procedures, but offer these procedures at exorbitant costs. Reducing cost while, at the same time, pushing the envelope as pioneers is a delicate balance.

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