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Intradiscal Electrothermal Therapy (IDET) for Lower Back Pain

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Introduction

Approximately 90 percent of Americans will develop lower back pain at some point in their lives.¹ An estimated one million Americans suffer from a specific type of chronic back pain attributed to damage to discs of the spine. Pain caused by damaged discs in the spine is complex and not completely understood. A new therapy now available shows promise for the treatment for lower back pain caused by specific types of disc damage. Called intradiscal electrothermal therapy (IDET), targeted intradiscal therapy, or intradiscal electrothermal coagulation, the procedure is based on a similar therapy used to treat patients with shoulder problems. As of December 2000, about 25,000 IDET procedures have been performed in the United States; about 350 of these have been performed in Minnesota.

Anatomy

The spinal column is made up of spinal nerves, ligaments, discs, and 33 bones called vertebrae. There are 7 cervical, 12 thoracic, 5 lumbar, 5 sacral, and 4 coccygeal vertebrae. Vertebrae are separated by discs, which act as cushions between the bones. Lower back pain is commonly found in the lumbar region of the back. Problems with the discs may be one cause of lower back pain. Disc pain may be a result of tears or bulges that put pressure on nerves.

A disc has an inner gel-like substance called the nucleus pulposus, which is surrounded by an outer annular ring (Figure 1). The annular ring consists of fibrocartilage and fibrous tissue held together by type I collagen. Discs cushion the vertebrae, stopping them from rubbing against each other when the body moves.

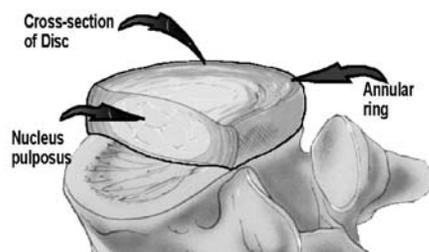
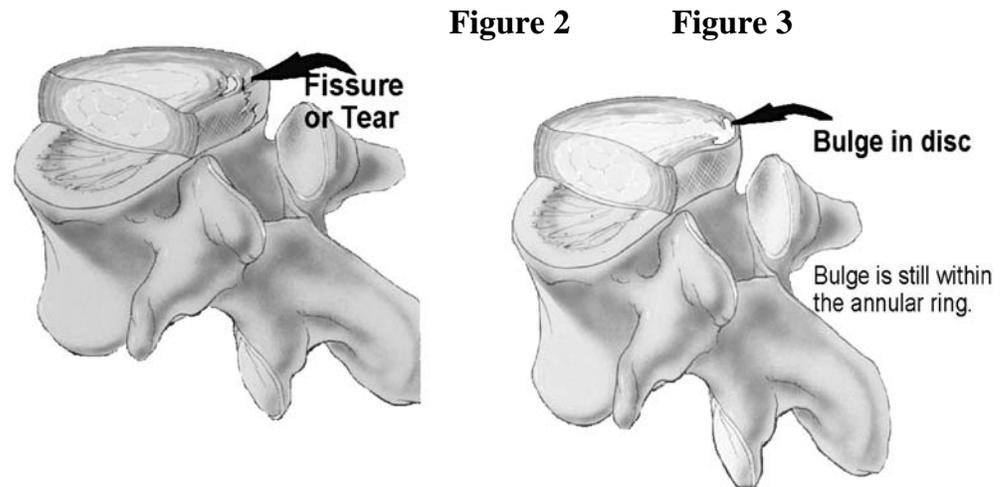


Figure 1

A weakness in the annular ring, such as a tear or fissure (Figure 2) may allow the gel-like substance to expand beyond its a bulge (Figure 3), which may place pressure on nerves. The tear or fissure may also result in the growth of nerves into the disc.² These nerves may then be pinched when the spine moves and pain may be felt.



Background

IDET is an outpatient surgical procedure developed for the treatment of chronic lower back pain originating in discs. The procedure uses the SpineCATHÔ, a flexible catheter with a moveable tip that contains a heating element. The catheter is used with a programmable generator that causes the tip to heat and monitors its temperature. The United States Food and Drug Administration (FDA) approved both devices for marketing in February 1998. The devices may be used to treat patients with symptoms from one or more discs, with tears or fissures in which the nucleus is contained, and where a disc is bulging but has not ruptured through the annular ring.³

The flexible catheter is guided into the disc through a needle (Figure 4). The catheter placement is near the annular ring tear or fissure. Once the catheter is in place, the temperature is gradually raised to 194° Fahrenheit (90°C) and maintained for a specified period-of-time. The manufacturer recommends no more than 17 minutes, with 16 to 16.5 minutes being common. The goal of the procedure is to shrink type I collagen, and destroy nerves,⁴⁻¹¹ resulting in decreased nerve compression and pain.¹ The procedure is generally performed under local anesthesia so pain can be reported while the temperature is being raised.

Position of heated
catheter within the disc.



Figure 4

After heating, the catheter is removed

and an antibiotic is injected into the disc to guard against infection. No other medications are usually prescribed at the time of the procedure.⁵

IDET studies are limited, with most information being provided by the manufacturer. Three studies averaging 33 patients each, performed follow-up patient satisfaction surveys at 6 months. Of the 100 patients, 58 reported that their back pain had decreased and 53 reported improved sitting times.^{5,6,12} Two of the studies showed that 24% of the patients had improved standing time and 40% had increased walking time.^{6,12} One study stated that 41% of patients reported improvement in sleeping.⁶ A fourth study showed that 89% of the 25 patients reported a reduction in pain at 3 months.⁷ Similar results have been reported when multiple lumbar disc procedures were performed.¹⁴ The studies showed that the most noticeable improvement occurred in the 3 to 6 months period.

What to Expect

Before IDET

Before IDET, a physical exam, as well as a number of tests should be performed to locate the cause of the pain, since the source of the back pain may be caused by a condition not suitable for IDET. A straight leg raise exam (SLR), a magnetic resonance imaging (MRI), and a discogram test (concordant pain reproduction with provocative discography at low pressurization) are performed. The discogram test injects a dye into the center of the disc suspected of causing pain and applies pressure to its annular ring. Pressure is applied to the weak disc until pain is felt. An indication of the disc condition can be determined from the amount of pressure used. Much discomfort will be felt during this procedure. Therefore, it is used only as final proof that the lower back pain is being caused by a degenerative disc.

After IDET

After IDET, back pain may increase because of the procedure. If patients have increased pain, inactivity and medication are required the first few weeks. The pain will generally decrease within two weeks, returning to the pre-IDET level. Pain should continue to lessen over the next six to nine months.^{5,12} During this time, it is very important not to put unnecessary stress on the treated disc or discs, and to follow the physical therapy recommendations.

Home therapy begins with walking and low intensity leg stretches. There will also be restrictions on sitting, restrictions on lifting or bending, and the use of a back support during the first month will be required. The second through the third months include a slow increase in floor exercises, a lessening of lifting limits, still no bending, and the use of a back support as

necessary. Athletic activities such as skiing, running, golf, and tennis are restricted until the fifth month, and then only with special instructions.^{15,16} Returning to work is dependent on the success of the surgery, the success of the physical therapy, and the condition of the adjoining discs. A return to a physically demanding job is usually not possible because of the pressures it may put on the treated site.

Patient Selection

Currently, there is not a clear-cut method for selecting patients to undergo this procedure. The FDA states that the IDET procedure is intended for solidifying and the decompression of disc material, and to treat patients with annular ring disruption of a contained bulge.³ IDET is designed to act only on discs and is not intended to treat other parts of the spine. Therefore, it should be used in patients whose primary source of pain has been confirmed to be from one or more discs in the lumbar section of the spine.

Examples of patient selection criteria include: function-limiting low back disc pain for at least six months and lack of satisfactory improvement with programs which include; progressive intensive exercise, at least one epidural corticosteroid injection, a trial of physical therapy, oral anti-inflammatory medication, and activity modification. Additional selection criteria includes: normal findings on neurologic examination, negative results on the SLR exam, a MRI scan that does not show nerve compressive lesion, and positive results of a discogram test.¹⁷

Candidates for the IDET procedure could be excluded if they have very narrow disc height, severe disc bulge through the annular ring, weak spine, very advanced stages of disc failure, various general health concerns, and those who have not first tried noninvasive treatments for a minimum of six months.^{3,18} Additional exclusions could include inflammatory arthritis, conditions, which mimic lumbar pain and medical problems, or disorders which would make the surgery and follow-up therapy difficult.¹⁶ Motivation has been found to be an important factor in patients being considered for IDET. Candidates must be able to manage the prescreening activities, and participate in a 12 to 16 week post procedural rehabilitation program, which utilizes progressive flexibility and strengthening activities.

Alternatives

There are few, long lasting alternatives which can lessen or eliminate lower back pain caused by tear or fissure of discs. Alternatives normally tried are: rest, medications, exercise/physical therapy, injections, activity alteration, braces, laser, arthroscopic thermal modulation, and fusion of vertebrae. IDET may be tried prior to fusion surgery.

Rest, medications, braces, activity alteration, and exercise/physical therapy, may address the pain but not the source. Injections may address the swelling and pain, but may not address the source. IDET, laser, arthroscopic thermal modulation, and disc fusion surgery are procedures that attempt to address the source of lower back pain.

Cost

Charges for an outpatient IDET procedure are approximately \$8000 per disc and include the facility, surgeon, equipment, anesthesia, and fluoroscopy. In comparison, patient charges for disc fusion surgery are approximately \$45,000.⁵ IDET is reported to have less complications and lost time from work than fusion surgery. There are additional costs associated with both procedures such as prescreening and physical therapy.¹

Presently, payment by medical insurance for the IDET procedure is decided on a case-by-case basis.

Safety and Complications

Although the procedure has been performed for three years, there are only minimal published data available. Studies (averaging 8 months; ranging from 6-16 months) indicate no harmful events or complications among study patients. In addition, no study patients developed nerve problems, or increased pain from the surgery after 6 weeks. Some patients experienced increased pain within the first two weeks and were treated with a single tapering course of oral prednisone.^{6,7,12}

Although the procedure looks promising, long-term effects are unknown, and no conclusions regarding long-term safety can be made.

As with any invasive procedure, IDET carries with it the risk of infection.

Studies show that when the IDET is ineffective, lower back pain has not been made worse.

Conclusions

While the initial data are promising, large randomized controlled trials are needed to determine safety, cost, effectiveness, and long-term outcome. Published research is limited and unrefined due to small sample size, poor study design, and lack of long-term data. Studies comparing IDET with other standard medical and surgical treatments are needed.

Pain relief, which varies, is experienced by some patients, but not all. Pain may return due to new or preexisting disc damage.

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