

DECOMPRESSION RESEARCH

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Emerging Technologies: Preliminary Findings

DECOMPRESSION, REDUCTION, AND STABILIZATION OF THE LUMBAR SPINE: A COST-EFFECTIVE TREATMENT FOR LUMBOSACRAL PAIN

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INTRODUCTION

Pain in the lumbosacral spine is the most common of all pain complaints. It causes loss of work and is the single most common cause of disability in persons under 45 years of age (1). Back pain is the most dollar-costly industrial problem (2). Pain clinics originated over 30 years ago, in large part, because of the numbers of chronic back pain patients. Interestingly, despite patients' reporting good results using "upside-down gravity boots," and commenting on how good stretching made them feel, traction as a primary treatment has been overlooked while very expensive and invasive treatments have dominated the management of low back pain. Managed care is now recognizing the lack of sufficient benefit-cost ratio associated with these ineffective treatments to stop the continued need for pain-mitigating services. We felt that by improving the "traction-like" method, pain relief would be achieved quickly and less costly. Although pelvic traction has been used to treat patients with low back pain for hundreds of years, most neurosurgeons and orthopedists have not been enthusiastic about it secondary to concerns over inconsistent results and cumbersome equipment. Indeed, simple traction itself has not been highly effective; therefore, almost no pain clinics even include traction as part of their approach. A few authors, however, have reported varying techniques which widen disc spaces, decompress the discs, unload the vertebrae, reduce disc protrusion, reduce muscle spasm, separate vertebrae, and/or lengthen and stabilize the spine (3-12). Over the past 25 years, we have treated thousands of chronic back pain patients who have not responded to conventional therapy. Our most successful approach has required treatment for 10-15 days, 8 hours a day, involving physicians, physical therapists, nurses, psychologists, transcutaneous electrical nerve stimulator (TENS) specialists, and massage therapists in a multidisciplinary approach which has resulted in 70% of these patients improving 50-100%. Our program has been recognized as one of the most cost-effective pain programs in the US (13). The average cost of the successful pain treatment has been cited as less than half the national average (13).

Our protocol combined traditional, labor-intensive physical therapy techniques to produce mobilization of the spinal segments. This, combined with stabilization, helped promote healing. In addition we used biofeedback, TENS, and education to reinforce the healing processes. We wanted to produce a simpler and more cost-effective protocol that could be consistently reproduced. The biofeedback and education could be easily replicated. The problem was producing spinal mobilization to the degree that we could decompress a herniated nucleus and relieve pain. Stabilization would come after pain relief.

The DRS System was developed specifically to mobilize and distract isolated lumbar segments. Using a specific combination of lumbar positioning and varying the degree and intensity of force, we produced distraction and decompression. With fluoroscopy, we documented a 7-mm distraction at 30 degrees to L5 with several patients. In fact, we observed distraction at different spinal levels by altering the position and degree of force. We set out to evaluate the DRS system with outpatient protocols compared to traditional therapy for both ruptured lumbar discs and chronic facet arthroses.

Figure 1. The DRS System.

Subjects. Thirty-nine patients were enrolled in this study. There were 27 men and 12 women, ranging in age from 31 to 63. Twenty-three had ruptured discs diagnosed by MRI. Of these, all but four had significant sciatic radiation, with mild to moderate L5 or S1 hyperalgesic. All had symptoms of less than one year.

The facet arthrosis patients also underwent MRI evaluations to rule-out ruptured discs or other major pathologies. They had experienced back pain from one to 20 years. Six had mild to moderate sciatic pain with significant limitations of mobility.

METHODOLOGY

Patients were blinded to treatment and were randomly assigned to traction or decompression tables. Traction patients were treated on a standard mechanical traction table with application of traction weights averaging one-half body weight plus 10 pounds, with traction applied 60-seconds-on and 60-seconds off, for 30 minutes daily for 20 treatments. Following the traction, Polar Powder ice packs and electric stimulation were applied to the back for 30 minutes to relieve swelling and spasm, and patients were then instructed in use of a standard TENS use to be employed at home continuously when not sleeping. After two weeks, the patients received a total of three sessions with an exercise specialist for instruction in and supervision of a limbering/strengthening exercise program. They were re-evaluated at five to eight weeks after entering the program.

Decompression patients received treatment on the DRS System, designed to accomplish optimal decompression of the lumbar spine. Using the same 30 minute treatment interval, the patients were given the same force of one-half the body weight plus 10, but the degree of application was altered by up to 30 degrees. The effect was to produce a direct distraction at the spinal segment with minimal discomfort to the patient.

Eighty-six percent of ruptured intervertebral disc (RID) patients achieved "good" (50-89% improvement) to "excellent" (90-100% improvement) results with decompression. Sciatica and back pain were relieved. Only 55% of the RID patients achieved "good" improvement with traction, and none excellent."

Of the facet arthrosis patients, 75% obtained "good" to excellent" results with decompression. Only 50% of these patients achieved "good" to "excellent" results with traction.

Table 1. Patient assessment of pain relief secondary to decompression and to traction.

Method Rating RID Facet arthrosis Decompression excellent 7 (50%) 2 (25%)

good 5 (36%) 4 (50%) poor 2 (14%) 2 (25%) Traction excellent 0 2 (25%) good 5 (55%) 2 (25%) poor 4 (45%) 4 (50%)
Excellent = 90 - 100% improved
Good = 50 - 89% improved
Poor = < 50% improved

DISCUSSION

Since both traction and decompression patients received similar treatment (except for the differences in the traction table versus the decompression table) with similar weights, ice packs, and TENS, the results are quite enlightening. The decompression system is encouraging and supports the considerable evidence reported by other investigators stating that decompression, reduction, and stabilization of the lumbar spine relieves back pain. The computerized DRS System appears to produce consistent, reproducible, and measurable non-surgical decompression, demonstrated by radiology.

Of equal importance, the professional staff facilities required, as well as the time and cost, are all significantly reduced. Since the more complex treatment program of the last 25 years has already been shown to cost 60% less than the average pain clinic, the cost of this simpler and more integrated treatment program should be 80% less than that of most pain clinics—a most attractive solution to the most costly pain problem in the US. In addition, patients follow a 30-day protocol that produces pain relief yet allows them to continue daily activities and not lose workdays.

SUMMARY

We have compared the pain-relieving results of traditional mechanical traction (14 patients) with a more sophisticated device which decompresses the lumbar spine, unloading of the facets (25 patients). The decompression system gave "good" to "excellent" relief in 86% of patients with RID and 75 % of those with facet arthroses. The traction yielded no "excellent" results in RID and only 50% "good" to "excellent" results in those with facet arthroses. These results are preliminary in nature. The procedures described have not been subjected to the scrutiny of review nor scientific controls. These patients will be followed for the next six months, at which time outcome-based data can be reported. These preliminary findings are both enlightening and provocative. The DRS system is now being evaluated as a primary intervention early in the onset of low back pain—especially in workers' compensation injuries.

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**Effects of vertebral axial decompression on
intradiscal pressure**

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The object of this study was to examine the effect of vertebral axial decompression on pressure in the nucleus pulposus of lumbar discs. Intradiscal pressure measurement was performed by connecting a cannula inserted into the patient's L4-5 disc space to a pressure transducer. The patient was placed in a prone position on a VAX-D therapeutic table and the tensionmeter on the table was attached via a pelvic harness. Changes in intradiscal pressure were recorded at resting state and while controlled tension was applied by the equipment to the pelvic harness. Intradiscal pressure demonstrated an inverse relationship to the tension applied. Tension in the upper range was observed to decompress the nucleus pulposus significantly, to below -100 mm Hg.

SURGICAL procedures utilizing conventional and percutaneous approaches have established the merits of decompression of intravertebral disc spaces in the management of low-back pain syndrom associated with lumbar disc herniation. 4, 12, 13, 15 Surgery will continue to play an important role in the treatment of patients with low-back pain and sciatica associated with herniated discs and degenerative disc problems. However, for patients who are not candidates for surgery, there is a need to establish a conservative approach that offers an effective means of returning the patient to a functional level of activity. Considerable controversy exists in regard to the various techniques currently employed. Aside from basic bed rest, there are a few noninterventional modalities that have been adopted as standards of therapy. Manipulative techniques for mechanical low-back pain associated with posterior facet syndrome of muscle strain have not been found as useful in the management of herniated or degenerated lumbar discs. Similarly, other modalities including ultrasound treatments, various electrical stimulation techniques, short-wave therapy, acupuncture, steroid injections, and the administration of anti-inflammatory agents and muscle relaxants all have a following among some practitioners but fall short of addressing the underlying problems associated with intervertebral disc lesions. All of these treatment methods fail by comparison to surgery, in our opinion, because they have the common problem of not relieving the pain from neurocompression or from the stimuli associated with a prolapsed nucleus pulposus. The only noninterventional method

that has been shown to hold any promise of relieving pressure on vital structures of the lumbar region is that of distraction of the lumbar vertebrae by mechanical forces applied along the axis of spinal column. 2,3,5,14

There has been some investigation into the effects of distracting segments of the spinal column excised from cadavers, 11, 14 as well as radiological studies that provided evidence that the application of certain forms of tension can distract vertebral bodies. 3,5 On the other hand, there are equally pertinent studies that failed to demonstrate any positive effects from other methods of applying spinal tractions. 1,10 Nachemson and Elfstrom⁶⁻⁹ have studied the effects of movement and posture on intradiscal pressure. Their measurements show pressure changes caused by positioning and posture range between 25 and 275mm Hg. Suggesting that some positions and postures may be inadvisable for patients suffering from lumbar disc lesions. Anderson, et al.,¹ and others have shown that certain traction techniques can actually cause an increase in intradiscal pressure, which would be undesirable in the treatment of low-back pain associated with herniated discs and a neurocompression etiology.

A new form of therapy, termed "vertebral axial decompression," has recently been introduced in the physical therapy department of the Rio Grande Regional Hospital. This treatment modality has shown considerable promise in relieving low-back pain associated with herniated discs or degenerative disc disease of the lumbar vertebrae in patients who are considered candidates for surgery. The purpose of this research project was to investigate the influence of this new treatment modality to intradiscal pressure in the lumbar spine of patients receiving this form of therapy. Fig.1 Photograph illustrating the equipment and the position of the patient as the system is activated. The caudal end of the table extends, applying tension to the pelvic belt. Upper body movement is restrained by having the patient grasp the hand grips. A graph of the tension applied is plotted by a chart recorder on the control console and the intradiscal pressure readings are entered on the same graph at the apex of each distraction curve.

Clinical Material and Methods

Five cases were selected from among individuals who were referred for a neurosurgical consultation and had previously sustained a work-related injury that resulted in herniation of a lumbar disc at one of more levels. The diagnosis in each case was confirmed by magnetic resonance imaging. The patients chosen were scheduled for percutaneous discectomy. Introduction of the cannula for the purpose of performing percutaneous discectomy offered an opportunity to measure pressure changes in the disc prior to the operative procedure.

The patient was prepared and a cannula was inserted under local anesthesia into the nucleus pulposus of the L4-5 intervertebral

disc using anteroposterior and lateral fluoroscopy to position the end. With the cannula in place, the patient was moved to a VAX-D table. The VAX-D equipment is routinely utilized in our nonsurgical treatment program for patients suffering from low-back pain. The equipment consists of a split table design with a tensionmeter mounted on the caudal, moveable section. The patient lies in a prone position and grasps hand grips to restrain movement of the upper body, which is supported on the fixed section of the table (Fig.1)

The cannula was then connected to a pressure monitor using a disposable pressure transducer. The lines were filled with normal saline. The pelvic harness designed for this therapy was fastened around the pelvic girdle and connected to the tensionmeter via straps attached to the harness. When the system was activated the caudal section supporting the lower body extended slowly, applying a distraction force via the pelvic harness connected to the tensionmeter. The level of tension was preset by the operator on the control console and observed and plotted on a chart recorder. The movement of the table was stopped and held when the desired tension was reached. An average course of therapy consisted of 30-minute sessions on the table once a day for 10 to 15 days. During each session the patient undergoes alternating cycles of distraction and relaxation, the timing and periodicity having been programmed by the therapist.

In this study various distraction tensions, ranging from 50 to 100 lbs, were used for vertebral axial decompression therapy. The distraction tensions applied were monitored on a digital readout and recorded on a continuous graph tracing by a chart printer incorporated in the control console. The resulting changes in intradiscal pressure in the L4-5 nucleus pulposus were observed on a digital readout on the pressure monitor, and the readings were entered onto the chart recording at the point when the apex of distraction tension was achieved. The pressure readings were then applied to the negative-range calibrated curves prepared for each transducer to derive accurate intradiscal pressure readings.

TABLE 1

Effects of lumbar traction on intradiscal pressure* *See Fig.2 for graphs of data points.

Measurements in the first two positions could not be translated accurately and are omitted (see text).

Fig.2 Graphs showing the intradiscal pressures recorded in the L4-5 nucleus pulposus of three patients (Case 3, *upper*; Case 4, *center*; and Case 5, *lower*) with herniated disc at this level. Pressure is plotted against distraction tensions consistent with the range of tension recommended as the therapeutic protocol of the equipment used in this study.

The biological transducers employed in this study are primarily designed to measure pressure changes in the positive range. Following each procedure the pressure monitor and the disposable pressure transducer used for each patient were individually calibrated and a correction curve was plotted showing the transducer readings versus actual pressures, to correct for the nonlinearity of the instrumentation in the range of negative pressures achieved. A pneumatic calibration analyzer with a accuracy of 2% was used for this purpose.

Results

Intradiscal pressure measurements showed that distraction tension routinely applied by the VAX-D equipment reduced the intradiscal pressure significantly to negative levels in the range of -100 to -160 mm Hg. The relationship between distraction tensions and intradiscal pressure changes for three patients is presented in Table 1. The extent of decompression (measured in mm Hg) shows an inverse relationship to the tension applied and may be expressed by a polynomial equation.

Discussion

Intradiscal pressure changes were monitored in five patients. When the first two patients were tested, it was not recognized that biological transducers produce nonlinear measurements in the negative ranges at the levels achieved in this study. Since the disposable units had been discarded it was not possible to translate the findings accurately: however the intradiscal pressures were observed to be significantly lowered. Also the findings were consistent with the later three patients, for whom the transducers were retained and individually calibrated, permitting accurate interpretation of the results.

An interesting observation was that changes in intradiscal pressure appeared to be minimal until a threshold distraction tension was reached. When the threshold was exceeded the intradiscal pressure was observed to decrease dramatically to levels in excess of 300 mm Hg below the positive pressure observed prior to the application of the pelvic tension. As indicated in the curves plotted for intradiscal pressures versus distraction tension, it appeared that the decrease in pressure tends to level off as the applied distraction tensions approached 100 lbs. The concept of a threshold distraction tension and the levels observed in these trials are consistent with radiographic studies of vertebral body separation reported in other publications.²

The results indicate that it is possible to lower pressure in the nucleus pulposus of herniated lumbar discs to levels significantly below 0 mm Hg when distraction tension is applied according to the protocol described for vertebral axial decompression therapy. These findings may offer a plausible explanation for the mechanism of action for this therapeutic modality. Future research is warranted to study the decompression phenomenon achieved with this technology and its relationship to clinical outcome in patients with anatomical dysfunction of the lumbar spine. We are preparing a follow-up study on the clinical efficacy of this treatment modality.

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Disclosure

The authors have no financial interest in either the equipment or the methodology advanced in this study.

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Back to the Future: Non Surgical Solutions to Spinal Disc Rehab with Spinal Decompression

Spinal Decompression is the most effective treatment for herniated discs and more doctors are looking into this breakthrough procedure that is 86%-91% successful without drugs or surgery.

(PRWEB) June 19, 2006 -- Working out can be a welcome release from stress and tension. But for those stricken with lower back pain, this experience can easily crank up your pain. Most gym enthusiasts know that once you injure a disc (the soft jelly material between your spinal vertebrae) it can severely limit your exerciseroutine and quality of life.

For many, this is due to collective loading of stress on to the spine – due to bad posture, repetitive tasks, and use of weighted machines. Over time, these activities begin to restrict normal motion, and the spinal discs deform as a result of pressure changes within the disc—leading to a loss of disc space and degenerative arthritis.

One of the reasons that your discs do not heal properly after an injury, is that as we age the blood supply to the disc diminishes. Without a proper blood supply, the tissue does not heal properly and the injured disc continues to degenerate. On the contrary, if you injure your muscle or bone, it heals in a shorter period of time, because of its blood supply. An example would be a fracture, once a bone is fractured the bone is stronger in the fractured area, than prior to the injury. On the other hand, when a disc is injured, it cannot heal properly and the result is a permanent weak link. Over time, excessive forces on the disc, can cause this injury to flair up and resulting in a life time of pain and suffering.

For many years, surgery has been the only option for pain relief. However, due to recent advances in medical technology, there is a new revolution in a non-surgical technique that is FDA approved and safe.

This new therapy is Spinal Disk Decompression.

The treatment uses specialized equipment to position the discs and ligaments to receive adequate blood flow to heal and strengthen .Decompression Therapy works to relieve pressure among herniated discs, ultimately allowing blood, nutrients and water to flow through the affected areas and increasing the ability to recover. A typical treatment requires a commitment of four to six weeks, each session lasting 25-45 minutes long. The patient relaxes on a decompression table, while watching his or her favorite DVD as the time passes. The treatment is a gradual process, gently allowing the herniated discs to return to their natural state. Clinical studies have been performed to evaluate the effect of spinal decompression on herniated discs.

The physical findings of patients with herniated and degenerative disc disease, show that 86% of patients who complete the therapy report immediate resolution of symptoms. Physical examination findings show improvement in 92% of patients over the course of treatment.

“These findings demonstrate a significant, lasting improvement, compared to the results derived from traditional surgery. In my opinion, this procedure has the potential to become a primary treatment for herniated disc injuries and spinal pain management.” explained Dr. Steven Shoshany, a Manhattan based Chiropractor and expert in non-surgical spinal disc herniation treatment.

The American health care system spends more than \$50 billion dollars annually on back pain treatment. According to the American Chiropractic Association, one half of all Americans admit to having back pain each year and chronic back pain is the number one disability in persons under age 45.

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PAIN MANAGEMENT
A Practical Guide for Clinicians
FIFTH EDITION
Chapter 20:

New Concepts in Back Pain Management:

Decompression, Reduction, and Stabilization

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Volume 1

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New Concepts in Back Pain Management: Decompression, Reduction, and Stabilization

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ABSTRACT

A thorough evaluation of previous traction techniques reveals no consistent pattern in prior literature. We have evaluated a variety of devices and found that seven major factors are important in achieving optimal clinical results. These include: (1) split table design to minimize effects of gravity; (2) flexion of the knees for hip relaxation; (3) controlled flexion of the lumbar spine during treatment which alters the location of distraction segmentally; (4) comfort and non-slippage of the pelvic restraining belt; (5) comfort and non-slippage of the chest restraint; (6) concomitant use of TENS, heat, ice, and myofascial release; and (7) a graduated limbering, strengthening, and stabilization exercise program. Using this system, successful pain control was achieved in 86% of patients studied with ruptured intervertebral discs and 75% of those with facet arthrosis.

INTRODUCTION

New advances centering on the use of specific segmental distraction as an adjunct to managing low back pain with and without neuropathic sciatica are reported here. These should be of special interest to both primary eye care and multidisciplinary medical specialists when symptoms persist despite comprehensive management of acute back pain.

The utility of physical modalities has been well established in many forms (Wall & Melzack, 1984); however, the use of traction techniques has been largely empirical. Relatively few studies have specifically discussed ergonomics and the biomechanics of spinal pathology as it relates to practical clinical outcomes employing powered or weight distraction forms of therapy.

Previous outcome studies have lacked the applied principles of quantifications and biomechanics that correlated clinical data with a specific diagnosis resulting from structural abnormalities such as discal herniation, lumbar facet arthropathy, foraminal stenosis, and motion segment abnormality syndromes or their comorbid combinations (Anderson, Schultz, & Nachemson, 1968; Lind, 1974; Bettann, 1957; Binkley, Strafford, & Gill, 1995). Anatomically, the low back is relatively clinically inaccessible.

A reevaluation of mechanical therapy is needed since the various etiologies have overlapping features. Different symptom complexes associated with dysfunction due to complex ipsilateral, contralateral, and segmental neural networking, as well as combines somatic and autonomic neural interactions, may serve to confound the clinician. A novel approach to mechanotherapy is presented to review these six considerations: (1) outcomes validation (2) relative safety, (3) ease to use by the patient or healthcare professional, (4) introduction of new principles of treatment, (5) appropriate utilization, and (6) cost effectiveness resulting in shortened morbidity with optimal improvement.

TYPES OF LOW BACK PAIN

Classically, there are four broad categories of low back pain syndrome, each requiring different treatment pathways (O'Brien, 1984; Bogduk, 1987):

1. **Acute muscular-low back pain** which is usually self-limiting
2. **Acute low back pain** involving sciatic radiation:
 - A. With neurological dysfunction
 - B. Without neurolog
3. **Chronic low back pain** which has recurring symptoms modified by therapy
4. **Neoplastic low back pain syndrome** that is recurring, but eventually becoming progressive, constant, and intractable.

Each type of low back syndrome has common features which vary with the intensity of symptoms: (1) regional pain, (2) impairment and mechanical dysfunction exacerbated by activities of daily living, and (3) mood and behavioral changes. All need to be addressed for overall successful outcomes.

PRINCIPLES OF BIOMECHANICS

Mechanical traction is the technique of applying a distracting force to produce either a realignment of a structural abnormality or to relieve abnormal pressure on nociceptive receptor systems (Colachis & Strohm, 1969; Cyriax, 1950; Gray & Hosking, 1963; Judovich, 1954; Nachemson, 1966). Frequently, both problems co-exist in differing combinations, which generates a number of clinical concerns. Should treatment be constant or intermittent? What is the reasonable duration of treatment? Should gravity or a weight formula based on the patient's weight be utilized to determine the amount of force for the treatment? Can both mechanoreceptors and chemoreceptors that produce unwanted symptoms be integrated and harmonized.

It has been previously described that the distracting force must be greater than the specific pathophysiology causing symptoms, and these mechanisms must be individualized for each patient (Judovich, 1995). Caution not to exacerbate symptoms should always be exercised. The old maxim "no pain, no gain" is both passé and disingenuous. The magnitude of the force correlates with the amount of distraction and must be closely monitored. At what force do we obtain better and more successful results, while reducing costs and morbidity? Katz et al. (1986) reported that 25% of the bodyweight as a traction force applied to 15 degrees positive elevation from the parallel prone plane for a 14-day series was found to be effective. We differ in our findings, as will be reported below (Katz et al., 1986).

When successful, the patient clinically reports symptomatic improvement of well-being and objective clinical verification of (1) improved range of motion, (2) reduction of verifiable regional muscle spasm, (3) improvement in regional tenderness by evaluating health professionals, and (4) improved neuropathic signs when compared to pretreatment findings. How can there be more individualized bioclinical integration? Pathophysiology of regional low back pain syndromes varies on a highly personal, individualized basis in such factors as etiology, causation, resulting activity dysfunction, and

psychopathological considerations. These factors must not be overlooked or underestimated in prescribing treatment.

HISTORY OF TRACTION

A review of the "Annotated Bibliography on the History of Traction" (Appendix A) summarizes 41 articles, from Neuwirth, Hilde, and Campbell in 1952 to Engel, Von Korff, and Katon in 1996.

The reader is referred to Appendix A for a review from medieval times to the present. A summary of this bibliography leads to the following conclusions:

1. Clinical outcomes are highly variable.
2. These are different types of traction techniques, such as intermittent or constant.
3. Variable angles of traction may be applied.
4. Differing weight sequences may be utilized.
5. Suspension devices are useful.
6. Time-scheduled sequences are described, but without specific guidelines and with many variables.

The present chapter is not intended to criticize the previous authors or data presented, but demonstrates that many variables being considered lack quantification. Neurological surgeons have gained extensive experience dealing with and managing problems of intracranial pressure using methods of quantification and have now applied those principles to the intradiscal pressure manometry for clinical correlation of low back pain syndrome.

The first application of quantification by relatively recent studies of quantitative intradiscal pressure changes has been reported by Ramos and Martin (1994). By cannulizing the nucleus pulposus of L4-5 and monitoring intradiscal pressure

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via a pressure transducer, three patients were observed to have lowered pressures below 100 mm Hg as a result of traction technique.

Other methods employing visualization were advanced by Gray (Gray et al., 1968) Radiological assessment of the effect of body traction was reported by Gray et al. (1968). Using only body's weight with a thoracic restraint and only a 12-degree incline, significant lengthening of the spine occurred within 5 minutes and even more significantly after this modified gravity reduction traction for 25 minutes.

Combined studies by Anderson, Schultz, and Nachemson (1968) of intervertebral disc pressure during traction demonstrated by radiographic studies concluded that disc space increases in height and lumbar disc protrusion can be reduced during traction. Myelographic evidence of disc herniation was found to disappear after traction (Anderson, Schultz, & Nachemson, 1968).

Shealy and Borgmeyer (1997) introduced a new biomedical application device that can apply all these positive effects to individual disc levels. To clinically document improvement, clinical data combined with radiofluoroscopy was employed. This new approach delivers precise treatment to decompress the lumbar disc space and then stabilize once asymptomatic through a program of physical rehabilitation.

THE DRS SYSTEM

The major goal of the DRS System (Fig. 1) is decompression, reduction, and stabilization of the lumbar spine. In a series of 50 patients with chronic pain, 23 having ruptured intervertebral disc and 27 with facet joint pain, it was noted that *conventional* spinal traction was less effective and biomechanically insufficient for optimal therapeutic outcome. Extensive observations led to the conclusion that five major factors were important for lumbar traction efficacy:

Fig. 1. The DRS decompression-reduction-stabilization device.

1. Separation of the lumbar component of the joint
2. Flexion of the knees
3. Flexion of the lumbar spine by raising the angle of distraction
4. Comfort and nonslippage of the pelvic belt

For patients with ruptured intravertebral discs who have not experienced significant improvement or at least a 50% reduction in their pain level after five DRS sessions (1 week), addition of colchicines is helpful; 1 mg of intravenous colchicines, with 2 g of magnesium chloride and 100 mg of vitamin B6, is administered daily for 5 days (Appendix C). If significant improvement occurs during the 5-day colchicines treatment, then the patient continues with the DRS system and continues to take oral colchicines (0.6 mg daily) for 6 months, along with magnesium oral spray (allowing at least 200 mg of magnesium for sublingual absorption daily.)

As an anti-inflammatory, we concentrate upon the use of bromelain proteolytic enzyme, 1,000 mg 30 minutes prior to each meal and at bedtime (Seligman, 1962; LotzWinter., 1990). If this is not sufficient, the patient may take any desired over-the-counter nonsteroidal anti-inflammatory drug (Benedetti & Butler, 1990). Obviously, patients often choose these and use a wide variety. The major complications of nonsteroidals include gastric erosion/ulceration and potential liver, kidney, and/or bone marrow toxicity.

CLINICAL RESULTS

In our study, 19 of 23 patients (86%) with ruptured intervertebral discs were markedly improved, and 75% of those with facet arthrosis (20-27) similarly reported a 50-100% reduction in pain.

These results are based upon a pain analog scale with patient evaluation before and no later than 1-4 weeks after completion of therapy. All patients with pain reduction of 50-100% showed improvement in flexibility and total physical activity.

CONCLUSION

A thorough evaluation of the literature reveals no clinical outcomes to correlate with different techniques. In our review and experience, no single device incorporates all seven major factors that are important in achieving clinical results. These include: (1) split table separation; (2) flexion of the knees; (3) flexion of the lumbar spine to raise the angle and distraction segmentally; (4) comfort and, nonslippage of the pelvic restraining belt; (5) comfort and nonslippage of the chest restraint; (6) concomitant use of TENS, heat, ice, and myofascial release; and (7) a graduated limbering, strengthening, and stabilization exercise program. Using this system, successful pain control is achieved in 86% of patients with ruptured intervertebral discs and 75% of those with facet arthrosis.

Because of space constraints, we did not discuss the psychological and psychiatric management of pelvic pain technique, and the reader is referred to other sources. It is worthwhile to consider also that by alternating the pathophysiology of the macro-mechanoreceptor-pain pathway, we may secondarily affect the chemoreceptors as well as reduce noxious stimuli of the richly enervated somatoautonomic lumbar spine, thereby reducing the chronicity of activity-related lumbar pain syndrom. This benefit may also reduce need for medications.

The new DRS system is a welcome addition to the problematic low back pain syndrome. The DRS system appears to be cost effective it merits more widespread utilization and awaits additional ergonomic studies. This approach can provide pain relief, and physicians are invited to take advantage of this gratifying treatment approach.

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APPENDIX A: ANNOTATED BIBLIOGRAPHY ON THE HISTORY OF TRACTION

- ⌚ Anderson, G.B.J., Schultz, A.B., & Nachemson, A.L.
(1968). Intervertebral disc pressures during traction.
Scandinavian Journal of Rehabilitation Medicine, Suppl.,
9 88-91

Pressures in the third lumbar discs were measured in individuals during active and passive traction. During active traction, an increase in pressure was always recorded, with increases corresponding to larger traction forces. During passive traction, the pressure remained close to the resting pressure, sometimes increasing and sometimes decreasing slightly.

An advertisement for something called a Back A Traction, a Swedish gravity traction table, currently being sold for \$995 (which is similar to an ad from 1978), states: "The unique feature of Back-A-Traction is a sliding backrest. You will experience and unloading of pressure from your joints and vertebrae even at an angle of 15 degrees." At 30 degrees, the traction is greater. The author states that the traction "relieves the pressure on pinched nerves and gives the vital fluids free access to lubricate your joints, helps align your pelvis and correct spinal curvatures, improves blood circulation, etc."

- ⌚ Batmen, E.H. (1975). Therapeutic advantages of intermittent traction in musculoskeletal disorders. *GP*.
XVI (5), 84-88

Treatment was directed at 210 patients with intermittent traction; 190 derived good results, with only 38 requiring some additional treatment. Sixteen of the 190 who did well required subsequent treatment after 3-6 months. In no case was any harmful effect observed. The author even reports improvement in patients with arthritis of the knees and hips, as well as stiff shoulders. Weak and constant pull was found to be ineffective, and strong and constant pull led to ligamentous overstretching and neurovascular tension, but intermittent gradual increasing pull, with complete relaxation and maximum traction, restored anatomic and physiologic equilibrium.

Contraindications were inflammation, infection, acute arthritis, trophic changes with disc protrusion, acute torticollis, myositis, and cases, which respond to the first treatment with increasing pain. For lumbar traction, the author reports that elevation of the patient's legs with flexion of the knees or supporting them at an angle of 45 degrees gave much more comfort. The average treatment was 30 minutes. Only 50 pounds of pressure was used in the lumbar spine.

- ⌚ Binkley, J., Strafford, P.W., & Gill, C. (1995). Interrater reliability of lumbar accessory motion mobility testing. *Physical Therapy*, 75 (9), 786-795.

In 18 subjects with low back pain, six different "orthopedic physical therapists" evaluated posterior-anterior accessory motion mobility at each of six levels, L1 to the sacral base, with the mobility being recorded on a nine-point scale. There were only 69% intraclass correlation coefficients. Conclusions are: "There is a poor interpreter agreement on determination of the segmental level of a marked spinouts process. There is poor Interrater reliability of P-A accessory mobility testing in the absence of corroborating clinical data. Caution should be exercised when physical therapists make clinical decisions related to the evaluation of motion at a specific spinal level using P-A accessory motion testing."

- ⌚ Bogduk, N. (1987). Pathological anatomy of the lumbar spine. *Clinical anatomy of the lumbar spine*. New York: Churchill-Livingstone. Bogduk defines mechanical disorders of the lumbar spine as follows.

Acute locked back: "A painful condition of sudden onset that occurs during attempted lifting." This pain is eased by flexion and aggravated by straightening.

Zygapophysial joint mechanism: He considers this Zeniscusentrapment, which is capsular traction, which may include a fibroadipose meniscoid tissue, which fails to re-enter the zygapophysial joint cavity after some type of movement. In such a case, "the meniscoid impacts the margin of the articular process and enters the subcapsular recess at the upper or lower pole of the joint." Again, flexion

reduces impaction. He points out that fragments of articular cartilage resembling the meniscoid may be formed in these joints and a plate of cartilage may be torn and moved.

Intervertebral disc mechanism: Another cause of an acute locked back might be posterolateral extrusion of disc nuclear material along a fissure in the posterolateral annulae.

Lumbar disc herniation: Expulsion through the annulus fibrosa of some portion of the nucleus pulposus. He comments that disc protrusion and disc prolapse are "sometimes used in relation to this phenomena -to imply subtle differences." He describes end-plate fractures, with vertebral end plates being more prone to fracture than failure of an annulus fibrosis. They are considered a "normal feature of aging and degeneration."

Disc degeneration: The mechanism by which due degeneration or degradation become symptomatic are additional stresses on the annulus fibrosis during weight bearing, flexion, and arthrosis of the zygapophysial joint.

- ⌚ Braaf, M.M., & Rosner, S. (1960). Chronic headache: A study of over 2,000 cases. *New York State Journal of Medicine*, 60, 3987-3994.

Braaf and Rosner consider that lesions of the cervical spine are one of the principal causes of persistent headache, chronic headache of cervical origin is a referred symptom caused by compression or irritation of one or more cervical nerve roots or portions thereof, trauma to the cervical spine is the prime factor in producing cervical nerve root irritation, and headache can be treated successfully by cervical traction. They state that 80% are completely relieved on a permanent basis with traction. Another 15% obtain satisfactory relief to carry on normal existence with this approach. They consider cervical traction specific for headache of cerebral origin and by far the most effective method, and maximum benefit is obtained only when it is carried out in a supine position. Traction should be performed as an office procedure, with treatment continued at least 3 months.

- ⌚ Braaf, M.M. & Rosner, S. (1963). *The Treatment of Headaches*. *New York State Journal of Medicine*, March 15, pp. 687-693

"In chronic headache definite, physical signs have been found consistently in the neck. Localized cervical tenderness, spasm of the muscles at the back of the neck, and restrictive movements of the neck are most common physical

findings...especially pronounced during the headache phase." A wide variety of abnormalities of the cervical spine, is seen. There are often motor, sensory, and reflex changes in the upper extremity. Major radiologic findings of the cervical spine are "usually very definite," especially on lateral films, both with the patient in neutral and with the head hyperextended, "similar to those found in lesions of the cervical disks." There is often loss of lordosis, narrowing of intervertebral spaces, osteophytic growths, and narrowing of intervertebral foramina, but at least loss of normal cervical curve is very consistent.

The best treatment in these authors' opinion is a combination of head traction and an intramuscular injection of 200mg of thiamin chloride. Thiamin chloride gives poor therapeutic results, but the addition of thiamin chloride to head traction makes the head traction more effective. Treatments "may have to be carried out daily, for the first week" and then three times a week for up to 2-3 months. "It has been demonstrated conclusively that head-traction, to be effective, must be carried out in the supine position." Sitting or standing traction often makes the patient worse. "The position of the head can be varied according to the angulation of the cervical curve" found on x-ray. That is, they change the angle to optimize normal lordosis. They use 5-60 pounds of weight, but never more than is comfortably tolerated. They begin with 5-10 pounds and gradually increase the weight. Aggravation of pain indicates too much force. They obtained complete alleviation of headache in 60% of patients, good results in an additional 30% (that means over

50% improvement), and poor results in only 10%. For migraine, figures are slightly less favorable" and therapy takes longer but they still consider this quite remarkable. They have found this type of head traction therapy effective in Horton's cephalgia, idiopathic headache, posttraumatic (post concussion) headache, tension headache, psychogenic headache, headaches due to temporal arteritis, atypical trigeminal neuralgia, sphenopalatine neuralgia, headaches due to cervical arthritis, and Meniere's syndrome.

Interestingly, the researchers reported that intranasal sphenopalatine ganglion block with 2% pontocaine helped, "even though this therapy never resulted in complete alleviation of the headache." They report that injection of 2% pontocaine hydrochloride in the upper cervical region is effective in relieving headaches in most cases, but results unfortunately are only temporary. Injection of 10 cc of 1% procaine intravenous over a 2 to 3 minute period was reported, with dramatic results in 100 consecutive cases. Exercise of neck muscles essentially maintains the improvement obtained in traction because the muscles are remarkably weak. "Exercises are directed toward strengthening muscles at the back of the neck as well as muscles of the shoulder-girdle." Diathermy and massage of the muscles are often helpful as well. They emphasize that the diagnosis of psychogenic headache is inappropriate, since many of these patients are cured with this type of treatment.

⊕ Braaf, M.M., & Rosner, S. (1965). More recent concepts on the treatment of headache. *Headache*, 5, 38-44

"Cervical traction is the most effective method, not only for giving symptomatic relief, but also for preventing the occurrence of headache on permanent basis... Chronic headache can be prevented by early recognition of the cervical lesion as a cause of the headache followed by adequate treatment directed towards the cervical spine."

④ Burton, C. & Nida, G. (1976) *Gravity lumbar reduction therapy program*. Minneapolis: Sister Kenny Institute.

In 1972, Dr. Burton started using a type of traction by a canvas chest harness, which he designed, in which he "hung" daily for 10 days a patient with a classic ruptured disc at L5-S1. This became the basis for gravity lumbar reduction, with the patient tilting upright in a chest harness, with the body's weight hanging below that from 30 degrees to 90 degrees. The harness was designed to have its lowest strap tightened under the rib cage and the upper straps grasp the rib cage to effect an equal distribution of pressure. They built up to a total of 4 hours of hanging traction per day and said that anything less than 4 hours with a minimum of 40 degrees elevation of the body was inadequate. They continued such treatment for 1-4 weeks, with those with ruptured discs being maintained an average of 10-14 days. The most significant complication was intolerance because of increased pain or a drop in blood pressure. They stated that the greatest value was when there was low back pain with sciatica due to a ruptured disc.

④ Colachis, S.C. Jr., & Strohm, B.R. (1969). Effects of intermittent traction on separation of lumbar vertebrae. *Archives of Physical Medicine & Rehabilitation*, 50, 251-258

Ten subjects (from 22-25 years of age) were placed in the Supine position with the thighs flexed 70 degrees and legs parallel to a split traction table. They used an angle of rope pull of 18 degrees and a traction force of 50 pounds applied for 10 seconds, followed by a rest period of 5 seconds, with traction given intermittently for 15 minutes. After a rest period of 10 minutes, a 100-pound traction force was applied in the same number for 15 minutes intermittently, and after another rest period of 5 minutes, another 100-pound traction force was applied continuously for 5 minutes. Lateral radiographs were taken before, during, and after the application of the traction force. There was a statistically significant increase in total mean posterior vertebral separation with 50 pounds of

traction force and a significant increase in total mean anterior and posterior separation when a traction force of 100 pounds was applied. The greatest increase in posterior vertebral separation during traction occurred at the L4-5 and the least at the L5-S 1 interspace with this particular approach with the rope at 18 degrees, but it is worth noting that there were changes all the way to T12-L1. For instance, at 100 pounds of intermittent traction, there was an increase in the posterior vertebral separation at T12-L1 of 0.7 mm, 0.4 at L1-2, 1.5 at L2-3, 1.4 at L3-4, 1.55 at L4-5, and 0.1 at L5-S1, an actual total elongation of the entire lumbar spine of 4.95 mm. With continuous traction of 100 pounds for 5 minutes after 5-minute rests, the mean total was 5.25 mm longer than prior to the traction.

⌚ Cyriax, J. (1950) The Treatment of Lumbar Disc Lesions.
British Medical Journal. December 23, 1434-1438

Cyriax states, "Sustained traction is the method of choice for ambulant patients with pulpy herniations whose symptoms warrant treatment. Distraction at the affected joint has two effects. (1) Increase in the interval between the vertebral bodies, thus enlarging the space into which the protrusion must recede. (2) Tautening of the joint capsule. Naturally, when the stack is taken up, the ligaments joining the vertebral bodies exert centripetal force all around the joint; this tends to squeeze the pulp back into place. Thus, sustained traction merely represents a way of achieving in a very short time the same effect as rest in bed for some weeks."

Bands around the mid-chest and pelvis with 200-300 pounds of pressure were applied for 2-3 periods of 20 minutes each, with 5 minutes rest in between. Treatment was carried out daily until the patient was well, usually 1-2 weeks. Sustained traction was described as using "the greatest possible traction" that the patient will permit for "as long as is reasonable."

- ④ Cyriax, J.H.(1955) Discussion on the treatment of backache by traction. *Proceedings of the Royal Society of Medicine*, 48, 805-814

Cyriax mentions that some people do better prone and some supine. Patients were treated once or twice a day for half to one hour each time. Traction weight may be only 100 pounds with a "small woman," but up to 200 pounds in a "large man." He emphasized, "As soon as the traction becomes effective, certain alternations in the pain are felt by the patient." The changes are that the pain usually ceases, but a unilateral lumbar pain may become central, a root pain may become a lumbar pain, a root pain may shorten (that is, move from the calf to the thigh above it), a root pain may remain in the same place but become less intense, or the pain may remain unaltered.

He emphasized that the patient must be treated daily; otherwise, it is not worth doing. He abandons treatment if pain is not improved after 12 sessions, and treatment is continued up to at least 4 weeks if necessary. In some patients with constant backache, adequate therapy may require 2-3 months.

The indications, in his opinion, are a protrusion of a disc, failure of manipulation, impaired nerve conduction (a weak muscle, absent ankle jerk, or cutaneous analgesia), failure of epidural local anesthetics, reference of pain to the coccyx or genital area, first and second lumbar disc lesions, and recurrence of pain after laminectomy. He considers contraindications to traction as "purely annular displacements," painful are during trunk flexion, pain caused by side flexion away from the painful side, pain which ceases as soon as the traction is applied but increases significantly when traction is released, and patients with impaired cardiac or respiratory function.

- ④ Deets, D., Haupt, K., & Haupt, S.S. (1977) Cervical traction: A comparison of sitting and supine positions. *Physical Therapy*, 57 (3), 256-261

These authors also feel that a supine position is much more effective than a sitting position.

There is greater posterior intervertebral separation, increased relaxation, decreased muscle guarding, and increased stability, with less force needed. Deep heat and massage prior to traction was recommended. They measured separation of the disc space in the same subjects sitting and supine, using 30 or 40 pounds of weight, and they got greater increase in interspace measurement in the supine position.

- ⌚ Dettori, J.R., Bullock, S.H., Sutlive, T.G., Franklin, R.J., and Patience, T. (1995) The Effects of Spinal Flexion and Extension Exercises and their associated postures in patients with acute low back pain. *Spine*, 20, 2303-2312

Subjects (149) with acute back pain were given flexion exercises, extension exercises, and postural extension exercises. There was no difference in outcome between flexion of extension exercise groups. However, either exercise was slightly more effective than no exercise.

- ⌚ Engel, C.C., Von Korff, M., & Katon, W.J. (1996) Back pain in primary care: Predictors of high health-care costs. *Pain*, 65 (1,3), 197-204

The authors studied 159 back pain patients consecutively presenting in a primary clinic of an HMO. Their conclusion is that a minority of primary care back pain patients' account for a majority of healthcare costs. Increasing chronic pain was the strongest independent predictor of high back pain costs. Increasing pain persistence and a disc disorder with or without sciatica were also significantly predictive of high back pain costs. Arthritis was weakly associated with high cost variables, compared to non-disc, non-arthritis pain. Increasing depression was weakly but not statistically associated with high back pain costs. They quote other statistics suggesting that the etiology of back pain is unclear in at least 79% of men and 89% of women. Only 2% of patients ultimately require surgery, and only 16.9% have a disc disorder and/or sciatica. They emphasize, "Often, however, prescribed therapies such as bed rest, opioid analgesics, and muscle relaxants or sedatives do not

reliably ameliorate chronic pain and may acutely diminish patient functioning."

- ⌚ Goldfish, G.D. Lumbar traction (source of this book undetermined).

Among other things, the author states that no significant distraction of the lumbar disc was produced at less than 50 pounds of traction. He mentions that Cyriax has hypothesized that traction could actually produce negative intradiscal pressure, strong enough to suck the herniated disc back in.

- ⌚ Gose, G. (1996) *Clinical study...The efficacy of V.A.X-D therapy.*

- ⌚ Chicago: University of Illinois, April 10.

The author states that 20 treatments of V.A.X-D therapy have been proven to be effective in about three-quarters of all patients who have any combination of facet syndrome, degenerative disc, or single disc herniation. Private transmittal. On April 12, 1978, the senior author received a package from Gravity Guidance, Inc. (816 Union, Pasadena, California). The material discussed an inversion gravity system where people were hung upside-down by the ankles. The following are statements from these materials: "Realign vertebrae, correct internal derangement-visceral, vascular, and skeletal, relieves pressure on nerves and articular surfaces. Permits the protrusion of the disk to be drawn back and heal in the proper position. Sucks the nucleus to a more central position-away from the sensitive posterior part of the annulus. Pulp protrusions are reducible by full body load. Increases the range of motion and joint play. Distributes pressure equally in all directions and dissipates force. Decompresses the body (SPINE). Increases the volume capacity of the nuclear space (disk). Reduces degenerative changes in the disk and bone." Attached to that is mention of a patent number, 3,380,447.

- ④ Gray, F.J., & Hosking, H.J (1963). A radiological assessment of the effect of body weight traction on the lumbar disc spaces. *The Medical Journal of Australia*, December 7, 953-955

These authors used a traction table with the patient supine. The thoracic harness holds the body as the table is tilted a foot down, so the patient's body is really doing the traction. They used only a 12-degree incline, and after 85 minutes they noticed that even a higher angle of 0 degrees gave no significant further lengthening, but 5 minutes at 12 degrees was quite significant. These results indicate that "compared with the horizontal supine position, the lumbar disc spaces were widened significantly at an incline of 12 degrees after traction for 5 minutes, and even more significantly after traction for 85 minutes."

- ④ Gupta, R.C., & Ramarao, M.S. (1978). Epidurography in reduction of lumbar disc prolapse by traction. *Archives of Physical Medicine & Rehabilitation*, 59, 322-327

Fourteen patients, 7 of whom had multiple disc protrusions and the others a single disc protrusion, were treated for 10-15 days with traction applied by bilateral skin traction with a heated plaster on both sides, with 60-80 pounds of weight and the foot of the bed elevated 9-12 inches. Patients with massive disc prolapse tolerated the heavy skin traction better than those with less protrusion. Ten of the 14 patients showed definite clinical improvements, with decrease in back pain and sciatica, normal straight leg raising, and complete or partial recovery of sensory deficit. In all these cases, the lateral epidurograms revealed normal anterior contrast column, and the PA epidurograms showed no defect in nine cases, showing that the disc had reduced to its normal position. In one case, although there was definite clinical improvement and decrease, there was still a slight persistent defect. Two patients with motor deficits showed improvement. In two cases, only minimal improvement in clinical condition occurred after the traction, and interestingly, their epidurograms showed persistence of the same defects. They showed an

average vertebral distraction during traction of 0.5 mm. The authors followed nine of the cases for 1-2 years with no recurrence of symptoms.

⌚ Hadler, N.M., Carey, T.S., Garrett, J., & the North Carolina Back Pain Project (1995) The influence of indemnification by workers' compensation insurance on recovery from acute backache. *Spine, 20, 210-215*
Of 1,633 patients seen, 505 were insured by workers' compensation. These 505 were compared with 861 who had been employed on any job for pay within 3 months of the onset of backache, but whose care was not underwritten. "Those with compensatable back pain were more likely to categorize their tasks as physically demanding and had taken more time off work in the month before the baseline interview. Recovery of the sense of wellness they enjoyed before the episode of back pain was delayed. Recovery of function or return to work was not delayed." The conclusion: "Each of these associations is a reproach to the fashion in which workers' compensation insurance for regional back pain serves the ethic that is its *raison d'être*."

⌚ Hirschberg, G.G. (1974) Treating lumbar disc lesion by prolonged continuous reduction of intradiscal pressure. *Texas Medicine, 70, 58-68*.
The author mentions treating several hundred patients with sciatica resulting from lumbar disc lesion. Conservative treatment usually consisted of bed rest and pelvic traction. There are no real details about traction, and he really emphasizes prolonged bed rest.

⌚ Hood L., & Chrisman, D. (1968). Intermittent pelvic traction in the treatment of the ruptured intervertebral disc. *Journal of the American Physical Therapy Association, 48 (1), 21-30*
"The present survey indicates that intermittent pelvic traction is of value in treating the patient with a ruptured intervertebral disc...The patient with a nerve root compression from above and list away from the affected side would be expected to have the best results." One year or more later, they

presented excellent results in 15%, good results in 52.5%, and poor results in 47.5%. Excellent meant a symptomatic and employed full-time; good meant symptoms greatly improved with occasional minor low backache and fatigue.

The treatment consisted of a heat with hydrocollator packs of ultrasound, followed by intermittent pelvic traction. The patient was placed on a traction table with the legs raised to flatten the lumbar spine. They used a canvas traction belt around the pelvis and a thoracic corset around the rib cage to restrain the upper body. Traction force was most frequently set at 65-70 pounds, although initial treatments were usually given at 55 pounds.

Interestingly, they show a photograph from 1544 with an accrued traction table with the patient being hanged from above. This looks very much like what Chuck Burton did. They quote Neuwirth et al., in which up to 220 pounds of traction was used. Judovich, back in the 1950s, presented a new method of intermittent traction, and he stated that a constant pull was intolerable to the average patient, but intermittent traction could be tolerated and would give improved results. Cyriax, as early as 1950, also suggested that sustained traction gave much more effective results than bed rest. Cyriax, used 200-300 pounds of pelvic traction for two or three periods of 20 minutes, with 5 minutes of rest between periods, given daily for up to 2 weeks. Cyriax stated that traction "creates an increased space between the vertebrae, permitting the return of the prolapsed material." He also stated that the tightened ligaments helped to squeeze the protrusion back in place. The authors also report a study by Christman et al. on patients with back pain, sciatica, and a positive sciatic nerve stretch test with either weakness or loss of a tendon reflex; 51% of the patients had good or excellent results with traction.

⌚ Judovich, B.D. (1954) Lumbar traction therapy dissipated force factors. *Lancet*, 74, 411-414

In the cervical area, this author reported that it required 30-40 pounds to demonstrate a beginning

widening of the intervertebral spaces. In the lumbar spine, he used 80-85 pounds of traction in most people, but at least 90 pounds or more in heavier patients. Keeping the bed level, he found that raising the legs in slings during the traction helped significantly. Even in heavy patients, it required 10 pounds less traction if the legs were flexed over a firm bolster. Hyperextension increases pain. Flexion of the spine decreases pain and improves results. In both live people and cadavers, "the average surface traction resistance of the body is approximately 54% of total body weight. The lower body segment-transverse section through L3, L4 interspace-weighs approximately 48% of total body weight. Approximately 54% of the weight of the lower body segment is also required to overcome its surface traction resistance. This is equal to approximately 26% of the total body weight. The force, therefore, that is dissipated with leg or pelvic traction is approximately 26% of the entire body weight. Only adequate weight in excess of this amount has a stretch effect upon the lumbar spine."

Ⓢ Judovich, B.D. (1995) Lumbar traction therapy-Elimination of physical factors that prevents lumbar stretch. *Journal of the American Medical Association*, 159 (6) 549-550

The author emphasizes that in a living being, the force necessary to overcome "surface traction resistance" is approximately 54% of the weight of the body. "Tone and elasticity of tissues appear to have no practical bearing upon the required force." Interestingly, he emphasizes that the lower body from the L3-4 interspace composes 49% of the entire body weight; thus, 26% of the entire body weight is calculated as an approximate average necessary to overcome resistance of the lower half of the body. This is called the "dissipated force factor." This particular force is "completely neutralized and lost as a stretch force to the lumbar spine." He emphasizes thus that the first 40-45 pounds are "lost" as a lumbar stretch force. Thus, he emphasizes further that one must exceed an average of 80 pounds of weight in order to begin to produce any type of effective lumbar traction.

Lawson, G.A., & Godfrey, C.M.(1958) A report on studies of spinal traction. *Medical Services Journal of Canada*, 14,762-771. These authors used spinal traction with weights up to 100 pounds on the cervical area and 150 pounds on the lumbar region for varying amounts of time and showed increases of up to 4 mm with the disc spaces in the lumbar area.

- ⌚ Lehmann, J.F., & Brunner, G.D. (1958) A device for the application of heavy lumbar traction: Its mechanical effects. *Archives of Physical Medicine & Rehabilitation*, 39, 696-700

These authors describe a hydraulic device that delivers heavy lumbar traction in an upright position. They state that "under traction the proper alignment of the vertebrae of the lumbar spine is maintained. The machine produced a statistically significant widening of the intervertebral spaces and a therapeutic stretch of the lumbar musculature."

- ⌚ Lidstrom, A., & Zachrisson, M (1970) Physical therapy of low back pain and sciatica. *Scandinavian Journal of Rehab Medicine*, 2, 37-42.

In 62 patients treated with sciatica, use of intermittent traction as recommended by B. Judovich in 1954, using one half of the body weight plus an additional 30-40 pounds of intermittent traction, revealed a "statistically they treated patients with "isometric training of the abdominal muscles." They used the Fowler position for the traction. Actually, the traction force was in general given over a 20-minute period with 4 seconds of hold and 2 seconds of rest. The traction force used for a patient weighing 50 kg was 58 pounds; for one weighing 55 kg, 61 pounds; for one weighing 60 kg, 63 pounds; and for one weighing 70 kg, 69 pounds. Basically, they had improvement in 100% of those treated with traction.

- ⌚ Lind, G., (1974) Auto-traction: Treatment of low back pain and sciatica. Dissertation. Sweden: University of Linkoping.

Radiographic studies performed during traction have demonstrated that the disc space increased in height and that lumbar disc protrusion was reduced. Myelographic evidence of disc herniation was found to disappear after traction. In active traction the subject's pelvis was fitted with a harness attached to a solid metal frame. The subject applied traction by pulling with the arms on another frame at the head end of the table. The pressure is exerted by the patient. They called this auto-traction. Patients were all lying on their left side when this was done. Passive traction was produced by two investigators, one pulling on the patient under the arms and the other on the pelvis. No specific weights in either case were listed.

④ Loeser, J (1996) Editorial comment: Back pain in the workplace II. *Pain*, 65 (1) 7-8

Dr. Loeser reports that "malingering is rare, delusions of pain ever rarer." He further goes on to state that 80% of the adult population has back pain at some time or another, and at any one time 14% have had back pain in the previous 2 weeks. Loeser states that the overwhelming majority of those who do submit a claim for their back pain return to work within a few weeks, but that there are two million chronic disabled back pain patients in the United States. "There is increasing evidence that the treatments rendered to those with nonspecific back pain have no efficacy." Loeser emphasizes that the rate of surgery for low back pain is directly related to the number of surgeons and not to the population. He also wagers "that the number of chiropractic treatments is related to the number of chiropractors, not citizens." He goes on to say that the same could be said for acupuncture treatments, physical therapy, or any other treatments for low back pain. "Healthcare is a social convention, driven only in small part of anatomy, pathology, or physiology." He believes that a "good argument can be made that our current method for diagnosing, treating, and compensating claimants with nonspecific low back pain leads to increased paid, suffering, impairment, disability, and costs.

Patients are told things by their doctors that lead to inactivity and depression."

- ⌚ Mathews, J.A. (1968), *Dynamic discography: A Study of Lumbar Traction. Annals of Physical Medicine. IX(7)* 265-279

These authors describe the radiographic findings in three patients with sciatica and used visualization with epidural contrast injections while the lumbar spine was injected to track. In two patients with multiple disc protrusion, protrusion was lessened by the traction, created by "vertebral distraction." Traction was applied with the patient prone on a conventional "couch.," with a thoracic corset and pelvic harness. They used traction of up to 120 pounds for 38 minutes, with the improvement as noted.

- ⌚ McElhannon, J.E (1984) *Physio-therapeutic treatment of myofascial disorders*. Anaheim Hills, CA: James E. McElhannon

McElhannon considers the contraindications to traction to be primary metastatic malignancy, cord compression, infections disease of the spine, cardiovascular disease, arthritis, old age, pregnancy, active peptic ulcers, hernia, aortic aneurysm, or gross hemorrhoids. But traction is indicated in conditions where you want to achieve "distraction of the vertebral bodies with enlargement of the intervertebral space producing an inward suction effect on the disk; stretching of muscles and ligaments with a tautening of the posterior longitudinal ligament exerting a centripetal effect on the adjacent annulus fibrosis; separation of the apophysial joints; and enlargement of intervertebral foramina." He recommends mechanical massage of the lumbar spine prior to traction.

He states that the angle of pull in cervical traction will vary from 5 to 50 degrees. In the upper three vertebrae, the angle will be 5-15 degrees. For cervical vertebrae 4 through 7 and dorsal vertebrae 1, 2, and 3, the angle would be 30-50 degrees. "The lower you treat in the cervico-

thoraco spine, a greater angle of pull is required, up to 50 degrees, for maximum and consistent results." Proper angle pull for thoracic-lumbar conditions is 15-50 degrees. To affect low thoracic and lumbar vertebrae 1 through 3, the angle of pull must be 15-30 degrees. To affect L3 through L5 and S1, the angle of pull must be 30-50 degrees. "The lower in the spine you treat, the greater angle of pull required." He believes that mechanical massage should not be done after traction. He also believes that static traction for 20 minutes is preferable to intermittent traction for patients with acute discogenic disease, severe radiculitis, or severe muscle spasms and that a patient with severe muscle spasm should never have intermittent traction. For more chronic problems, intermittent traction (pulling for 30 seconds, followed by release of 10 seconds) is best and gives the greatest results. In the cervical area, he states that traction of the cervical spine should never start with less than 15 pounds, and never less than 50 pounds in the lumbar, as this poundage is necessary to overcome muscle tension, and less pounds will actually aggravate the patient by introducing reflex spasm. He recommends 3 days of steady traction and then three times a week for 6-8 weeks, with considerable improvement expected after three to five treatments. If the patient does not improve after three treatments, the poundage is increased by 10 pounds. Cervical traction goes up to 60 pounds, and even higher in large male patients, and lumbar traction goes up to 125 pounds. He states that some type of bolster should always be placed under the patient's knees to flatten the lordotic curve while traction is being given.

⌚ Nachemson, A. (1966) The load on lumbar discs in different positions of the body. *Clinical Orthopedics and Related Research*, 45, 107-122

"The load on the lumbar discs is related both to the body weight of the subject and the position of the body...For a subject weighing 70 kg, the load on the L3 disc in the sitting position is approximately 140

kg. Approximate loads in the other positions are as follows: standing, 100kg; sitting and forward tilting of 20 degrees, 190 kg. With an additional kg in hands, 270 kg; reclining, lateral decubitus, 70kg; relaxed supine, anesthetized reclining, 20 kg. If such a subject tilts forward 20 degrees in the standing position and lifts 50 kg by his hands, the total load on the L3 disc will be about 300 kg." In moderate degenerative discs, the pressures are approximately 30% lower than in comparable normal discs.

- ⌚ Nachemson, A.L.(1981) Disc pressure measurements. *Spine*, 6, 93-97

Intradiscal pressure was measured in over 100 individuals, and it was found that reclining reduces the pressure by 50%-80%, but unsupported sitting increases the load by 40%. Forward lifting and weight lifting increased the pressure by more than 100%, and upward flexion and rotation by 400%. "Large augmentations in pressure were also observed in subjects performing various commonly prescribed strengthening exercises."

- ⌚ Nachemson, A., & Elfstrom, G. (1970) Intravital dynamic pressure measurements in lumbar discs. A study of common movements, maneuvers, and exercises. *Scandinavian Journal of Rehabilitation Medicine, Suppl. 1*, 1-49

This publication refers back to the original material much of which has already been presented in other papers by Nachemson, but it is a much more comprehensive review.

- ⌚ Neuwirth, E., Hilde, W., & Campbell, R (1952) Tables of vertebral elongation in the treatment of sciatica. *Archives of Physical Medicine*, 33, 455-460

The authors state that the intervertebral discs constitute about one-fourth of the entire length of the vertebral column. They record data referring to vertebral traction as early as the fifth century B.C. in the writings of Hippocrates. He described various procedures to

redress kyphosis and in particular recommended the use of a ladder to which the patient was bound, head up or down, and then lifted by a rope, which ran over a pulley attached to the roof of a house. Then the ladder with the patient was dropped onto a hard pavement.

They describe a table, which can be tilted in either direction, head up or head down, using a hand wheel on a worm gear. They mount pulleys at either end of the table to pass straps to the head or the chest or the pelvis.

They always provide preliminary use of heat and sedative massage to the area of the vertebral segment to be elongated and then apply traction, with the intensity gradually increased. At the end of a few minutes, the traction is slowly and gradually reduced to the starting point. Then, after a short pause, traction is reapplied and increased to a higher level, with progressive stages to maximum traction, with 30-60 minutes of rest at the completion of the complete treatment. They gave treatment daily or every other day, and they report that "vertebral elongation" relieves muscle spasm, promotes the return of the protruded disc and the slightly displaced vertebrae to their original lodging, and facilitates reduction of subluxated apophysial joints, with reduction of pressure upon nerve root blood vessels and lymphatic and consequent relief of pain.

They report that in a cadaver stripped of muscles, 9 kg of traction force was necessary to separate two lumbar vertebrae by one and a half mm. In the living, 100 kg of traction force must be employed to obtain the same results.

They report overall, from their work and that of others, 68% good results in some 400 patients, 69% in another 240 patients, and 58% in another 156 patients. They state that vertebral traction has been found to exert significant beneficial effect in patients with sciatica.

④ Pal, B., Mangion, P., Hossain, M.A., & Diffey, B.L
(1986). A controlled trial of continuous lumbar

traction in the treatment of back pain and sciatica.

British Journal of Rheumatology, 25, 181-183

These authors compare a controlled trial of continuous lumbar traction in the hospital in patients with back pain and sciatica with a similar group treated with sham traction. However, they used only a maximum of 8.2 kg, which obviously would be of no value.

⌚ Ramos, G., & Martin, W. (1994) Effects of vertebral axial decompression on intradiscal pressure. *Journal of Neurosurgery*, 81, 350-353

A cannula was connected to the patient's L4-5 space with a pressure transducer. The patient was placed in a prone position on a VAX-D therapeutic table. Changes in intradiscal pressure were recorded. At a resting state, controlled tension was applied to the pelvic harness. Tension in the upper range was observed to decompress the nucleus pulposus, to below -100 mm Hg. This was only done in three patients.

⌚ Snook, S., (1987). The costs of back pain in industry. Occupational back pain, state-of-the-art review. *Spine*, 2(1), 1-5

In 1987, the average direct healthcare and compensation cost for an individual with back sprain was \$5,739. The estimated cost of industrial low back pain in the United States in 1983 was \$25.25 billion.

The author quotes an estimate of \$14 billion expended on the treatment and compensation of low back pain sufferers in 1976, with an estimate of \$25.25 billion in 1983. Lost wages alone were estimated at \$11 billion per year in 1975-78. In 1985, it was estimated that 33% of the cost of managing compensatable back pain due to medical care and 67% to "indemnity costs." It appears that we could conservatively estimate that compensatable back pain, both in medical costs and lost wages, in 1996 would be around \$100 billion. If we include non-compensatable back pain, which is at least another similar amount, the total cost of significant back

pain in the United States in 1996 would be somewhere between \$200-300 billion, counting wages lost or paid out, as well as medical costs, with approximately one-third of that total amount being total medical costs.

An ad from Spinal Designs International (2400 Chicago Avenue, S., Minneapolis, MN 55407) states that the LTX 3000 Lumbar Rehabilitation System (a chair in which the patient sits with a belt around the chest and the bottom of the chair drops out) leads to "lumbar stabilization, intradiscal pressure unloading, free movement and exercise, gentle musculature stretching, and neutral spine positioning."

⌚ Wall, P.D.(1996) Editorial comment: Back pain in the workplace. 1. *Pain*, 65(1),5

Commenting on a task force on "Pain in the Workplace," Dr. Wall states that the "report is an uncritical lurch back 150 years when chronic pain without lesions was already a major problems." He mentions that Charcot considered angina and Parkinsonism to be neuroses because of unknown causative lesion. He further quotes Tate describing back pain without lesion as hysteria, but could be caused by "irritation of the upper dorsal portion of the spinal marrow." Wall goes on to state that the authors of the task force "display no caution in their uncertainty that there is no lesion" and that "there is nothing left to study." He criticizes the task force's consideration of low back pain as "a problem of activity intolerance, not a medical problem." Dr. Wall advises that surgeons should not operate under such circumstances and not prescribe drugs, and he particularly criticizes the fact that the task force recommends abruptly at 6 weeks that "those still complaining of non-specific low back pain should be labeled activity intolerant and unemployed with a removal of medical and wage benefits." His conclusion is that "Back pain in the Workplace" is at the best an idiosyncratic, largely untested series of recommendations on how to treat the first six weeks of low back pain, after which advice ends abruptly with the re-assignment of the

patient to the diagnosis of 'activity intolerance' which is "not a medical problem."

- ⌚ Weisfeldt S.C. (1971) Ambulatory approach to the treatment of low back pain. *Journal of Occupational Medicine*, 13, 384-387

Ice packs and traction were used for acute back pain. The use of ice and later moist heat with intermittent traction plus ambulation and exercise afforded excellent relief of pain and earlier return to work, even in industrial accidents. Patients received an average of 8.3 treatments Of 316 industrial accident patients treated by intermittent traction and ice, 76.6% lost an average of 5.9 days of work.

- ⌚ Unpublished study. An acute low back distress study from the University Hospital, London, Ontario, 1987-1988 This unpublished study reports that 66% of patients had a positive outcome from VAX-D therapy. The criterion for success was a reduction to 50% of the baseline aggregate score for pain and disability.

APPENDIX B: BACK PAIN PROTOCOL

I. Inclusion Criteria

- A. Pain present for 1 week or more due to ruptured intervertebral disc
- B. Pain present for 1 month or more for other causes of back pain
- C. Patient will be available for 4 weeks of continuous therapy
- D. Patient has adequate financial resources to cover therapy
- E. Patient is at least 18 years old or has parental consent if at least 15 years

II. Exclusion Criteria

- A. Pregnancy
- B. Prior lumbar fusion
- C. Metastatic cancer

- D. Severe osteoporosis, with estimates by radiological interpretation of lumbar plain x-rays showing greater than 45% bone loss
- E. Bilateral spondylolisthesis of spondylolysis
- F. Compression fracture of lumbar spine below L1
- G. Aortic aneurysm by physical examination or x-ray
- H. Pelvic or abdominal cancer
- I. Rheumatoid spondylitis
- J. Disc space infection
- K. Significant cognitive dysfunction
- L. Psychosis
- M. Significant opioid, alcohol, or tranquilizer dependency
- N. Weight greater than 290 pounds (possible exclusion at 250 pounds depending upon weight distribution)
- O. Significant uncontrolled intercurrent medical disorder
- P. Hemiplegia or significant Para paresis
- Q. Severe peripheral neuropathy

III. Negative influences

- A. Smoking-Patients need to know that results will be 50% less effective
- B. Consumption of greater than 20 mg/day equivalent of diazepam or four Percodan/Percocet/Tylox (oxycodone/aspirin or acetaminophen), which will require a detoxification plan
- C. Consumption of greater than two cups of coffee, three cups or glasses of tea, or two cans of soda pop per day
- D. Obesity of greater than 20% above ideal body

- E. Consumption of prednisone or steroids than DHEA
- F. Overall poor nutrition
- G. Serious language barrier preventing effective communication
- H. Significant negative attitude on the part of the patient

IV. Evaluation

A. History

1. Comprehensive general medical assessment
2. Spinal-specific questions/ issues
 - a. Details concerning the onset of the pain complaint
 - b. Factors which decrease or increase pain
 - c. Location of center of pain, spread, and/or radiation
 - d. Intensity (average, high, and low, with estimate of percent of time being high or low)
 - e. Physical limitations due to the pain
 - f. Mattress (type, quality, and condition)
 - g. Sensory symptoms (tingling, numbness)
 - h. Known muscle weakness
 - i. Bowel, bladder, and sexual dysfunctions
 - j. Recent or remote spinal injuries
 - k. Recent or remote spinal surgery
 - l. Recent or remote diagnostic spinal studies (lumbar puncture, discogram myelogram ,CT, MRI, plain spinal x-rays)
 - m. Any spinal anesthetic or epidural or steroid injections
 - n. Trigger point injections or nerve blocks in the past 6 months
 - o. Acupuncture therapy in the past 6 months

- p. Any physical therapy in the past 6 months
- q. Any use of a back brace (other than work-required lifting belt) in the past 6 months
- r. Family history of significant spinal problems
- s. Any personal history of cancer
- t. Any personal history of collagen disease (rheumatoid arthritis, systemic lupus erythematosus, scleroderma, mixed collagen vascular disease)
- u. Any chiropractor or osteopathic adjustments initially determined dosage or manipulation in the past 6 months 2. All patients will start Bromasea 2 t.i.d. ½ hour

B. Physical Examination

1. General exam

- a. .Vital signs (height, weight, blood pressure, pulse, respiration, temperature)
- b. HEENT
- c. Neck
- d. Chest (heart, lungs, and breasts)
- e. Abdomen

- f. Pelvic (within past 6 months for women)
- g. Rectal (essential for all patients)
- h. Skin (lesions, thickness/coarseness, redness)
- i. Extremities (pedal pulses, cyanosis, clubbing, edema)
- j. Neurological
- k. Funduscopic CN II-XII
- l. Muscle Strength
- m. Tandem gait with Romberg screen
- n. Posture
- o. Sensory vibration at patella versus malleoli, light touch versus pin-prick for arm compared to leg dermatomes

2. Spinal

- a. Lumbar flexion, extension, side bending and lateral rotation
- b. Straight leg raising (lying supine and sitting upright)
- c. Hip abduction ("Fraser")
- d. Palpation of sacrum for sacral shear or torsion
- e. Palpation for rotation focal tenderness of the spine

3. Diagnostic Testing

- a. Plain x-rays of the lumbar spine, including oblique and flexion/extension laterals done within the past 6 months of after most recent injury or spinal surgery

- b. If there is a clinical suggestion of nerve root impairment, then obtain MRI from T12 to L1 to L5-S1
- c. CBC and differential, chemistry panel 20, ESR with 200-mm column, urine analysis, TSH, intracellular Mg (Spectral Diagnostics)
- d. If MRI is negative for nerve root compression in a patient with severe nerve root signs, then get EMG, NCV to rule in/out a neuropathy

4. Treatment

- a. Initial management of all currently consumed analgesic medications and substances (caffeine, alcohol, tobacco, and street drugs)
 - a. Patient will decrease by 10% per day from initially determined dosage.
 - b. All patients will start Bromase 2 t.i.d half hour a.c
- b. Patients will be taught to use the visual analog scale for pain measurement at the first appointment with the physician, and then will continue to complete visual analog scales at all subsequent appointments.
- c. Patients will be issued a TENS unit to be used during all waking hours
 - a. Electrode placement will be taught to patient by facility MD or RN.
- d. Patients will receive a daily pre-DRS vibratory massage or myofascial release using vacuum/ inferential current treatment for 30 minutes with heat application to the lower back for 20 sessions.
- e. Patients will be positioned on the DRS and receive distraction/decompression for

30 minutes using one-half of the body weight plus 10 pound for 20 sessions.

- f. After DRS, patients will have a Polar Pack placed on the lower back for 30 minutes.
- g. After 1 week (five DRS sessions) if patients with clinical and diagnostic imaging findings of ruptured or ruptured intervertebral disc are not 50% improved, add 1 mg/day intravenous colchicines and 2 g magnesium/ B6 intravenous for 5 days, then orally maintain patients on 0.6 mg/day for 6 months.
- h. After the second week of the program (ten DRS sessions), if improved 50%, instruct the patients in the Shealy exercise program. For those not yet improved 50%, then reassess patients with repeat physical examination
- i. For those patients who are *not* 50% better after ten DRS sessions, consider:
- j. Percutaneous electrical nerve stimulation to be done by the facility physician
- k. Referral to anesthesiologist or neurosurgeon for facet nerve blocks
- l. Trigger point injections with Sarapin by facility physician
- m. Enroll patient in laser study protocol and administer laser therapy 2 minutes/day for up to 5 days
- n. After 20 DRS sessions or significant improvement of patients symptoms from multimodality approaches, patient will have an exit physical examination with the facility physician. An aftercare plan will be established calling for the use of the Polar Packs, TENS, exercise, relaxation training, use of any substances, pacing techniques, and proper

utilization of body mechanics and posture for daily activities.

- o. Patients return 1 month after treatment for evaluation by the facility physician.

APPENDIX C: REFERENCES REGARDING COLCHICINE

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Topic Simple pelvic traction gives inconsistent relief to herniated lumbar disc sufferers.

A new decompression table system applying fifteen 60 second tractions of just over one half body weight in twenty 1/2 hour sessions was reported to give good or excellent relief of sciatic and back pain in 86% of 14 patients with herniated discs and 75% of 8 with facet joint arthrosis. (Shealy, C.N., Borgmeyer, V., AMJ. Pain Management 1997, 7: 63-65).

Herniated and degenerated discs can be shown at discography-disco-manometry to have elevated intradiscal pressures made even worse by sitting and standing, thus preventing proper disc nutrition. Therefore decompressing the over pressurized disc should allow for healing and repair of disc prolapse, herniation and annulus tears.

Serial MRI imaging of 20 patients treated with the decompression table shows in our study up to 90% reduction of subligamentous nucleus herniation in 10 of 14. Some rehydration occurs detected by T2 and proton density signal increase. Torn annulus repair is seen in all. Transligamentous ruptures show lesser repair. Facet arthrosis can be shown to improve chiefly by pain relief. Follow up studies for permanency or relapses are in progress.

The DRS Mechanical Decompression-Distraction System was described by Shealy and Borgmeyer (1) to give relief of lumbar herniated disc and facet joint arthrosis superior by 50% to conventional pelvic traction. Twenty DRS treatments produced on midsagittal MRI a 50% reduction in one case, and a 7mm distraction of L5 on SI was shown on lateral x-ray. (2) Clinical improvement in 75 to 85% of subjects was reported.

Does clinical betterment correlate directly to improvement in MRI image and can MRI shed any light on the mechanism of improvement?

That the abnormal disc has an elevated pressure can be appreciated at discogram. It is postulated that this elevated pressure interferes both with diffusion of nutrients from surrounding vessels into the nucleus and with adequate patching or repair of the torn annulus.

Nachemson's group has emphasized lowering intradiscal pressure for 30 years. (3) & (4) Neurosurgeons Ramos and Martin (5) at operation on a similar decompression table measured in an L4-5 herniated disc a lowering of intradiscal pressure from 30 to 50 mm above the normal 90 to 100 mmHg into the negative range of minus 100 to 150 mmHg during 90 to 95 LB traction. Will such negative pressures heal the annulus, rehydrate the nucleus?

The aim of the present study was to do before and after MRI to correlate clinical improvement with any MRI evidence of disc repair in annulus, nucleus, facet joint or foramen as a result of DRS treatment.

A course of 20 DRS Lumbar De-compression treatments were given in 4 to 5 weeks to 18 patients, and a double course of 40 in 10 weeks to 2 more. Pull of distraction was adjusted to one half-body weight plus 10 lbs. Each session consisted of 20 repetitions in 30 minutes of full distraction for 60seconds and 30 seconds of relaxation to 50 lbs. Distraction angle on pelvic harness was varied from 10% for L5-S 1 to 20 to 25% for L4-5 herniations and above.

Subjects comprised 12 males and 8 females from age 26 to 74. Radiculopathy in 14 patients was from herniated discs of varying sizes. (L5-S 1 level in 6, L4-5 in 6, and 1 each at L3-4 and L2-3).

Radiculopathy without disc herniation was present in 6 patients from foraminal stenosis facet arthropathy and lateral spinal stenosis.

EMGs confirmed radiculopathy in all.

MRI's before and after were obtained on high and mid field units.

Clinical status was assessed before, during, and after treatment with standard analog pain rating scale of 0- 10 and neuro exam.

Range of motion for spinal mobility (initially impaired in all), myotoma I weakness reflex and dermatomal sensory loss were tested.

A) MRI OUTCOMES

Disc Herniation: 10 of 14 improved significantly, some globally, some at least local at the site of the nerve root compression. Measured improvement in local or general disc herniation size varied in range of 0% in 2 patients, 20% in 4 patients, 30 to 50% in 4 patients and a remarkable 90 % in 2 patients who had the number of treatments at 40 sessions in 8 weeks. Fig. 1 shows an example of a local left lateral recess disc herniation reduced over 40% completely relieving root compression when the midline portion was a little changed.

Fig. 2 shows on axial view at L5/S1 retraction of a far left lateral herniated disc pulling it away from impingement on the S1 and probably L5 roots with complete relief of radicular signs and symptoms. Mid sagittal components was unchanged. Figs. 3 A & B & Fig. 4 show remarkable effects of 90% global disc reduction, perhaps due to extended course of treatments. Note the unique "empty pouches" left by the persistently bowed-out ligament at L4-5. Also some early rehydration of the degenerated nucleus is shown in Figs. 3, A & B and 4 by T2 and proton signals.

Facet joint arthropathy and foraminal compression cases showed no demonstrable change save 2 cases with slight increase in height but not in hydration.

B) CLINICAL OUTCOMES

Irrespective of MRI status all but 3 patients had very significant pain relief, complete relief of weakness when present, and of immobility and of all numbness (save in 1 patient with herniation and 2 with foraminal stenosis without herniation). With disc herniation, 10 patients of 14 had 10 to 90% improvement in pain and disability. Two had 40 to 50%, one had only 20% with foraminal syndrome without herniation, 4 had 70 to 100 % improvement, one had 40 to 50 %, one with severe spinal stenosis had only 25% and was sent for surgery. Degree of clinical im

Improvement from DRS treatment clinical outcome of radiculopathy whether from disc herniation or foraminal syndromes is more impressive than most improvement shown consistently by MRI, at least with today's techniques and short time of follow-up.

Relief of pain and disability by reduction of disc size is easy to argue in a small majority of this series. A few patients have dramatic anatomic improvement. The others with minimal or no significant MRI improvements are harder to explain. Also, many patients improved very early in treatment, probably before MRI change could be seen.

Nutrient diffusion increase and torn annulus healing resulting from lowering intradiscal pressures are likely causes of clinical improvement when MRI anatomy is not much altered by distraction. Leaking of important sulfates and carboxylates from the nucleus and posterior annulus have been shown in recent studies (6) and (7) lowering of intradiscal pressure by DRS treatment likely can start to reverse these processes by allowing fibroblast repair of the annulus outer layers and some nutrition to the nucleus.

Also penetration of nerves into inner annulus and nucleus of degenerated prolapsed discs has been recently demonstrated and could play a role in pain production. (8) Mechanical intradiscal pressure relief may help this feature as well as giving structural stability.

(1) DRS distraction treatments afforded good or excellent relief of pain and disability whether from herniated disc or foraminal or lateral spinal stenosis.

(2) MRI showed imperfect correlation with degree of clinical improvement but 10 to 90% reduction in disc herniation size could be seen at least at the critical point of nerve root impingement in 10 of 14 patients.

(3) Two patients with extended courses of treatment showed 90% disc reduction and one of these had early rehydration of the degenerated disc at L4-5. An "empty pouch" sign on MRI at the site of previous herniation was seen in these 2 patients.

(4) Foraminal and lateral spinal or facet arthrosis cases causing radiculopathy without herniation also improved but without MRI change.

(5) Annulus healing or patching in the herniated disc can be shown by MRI and is postulated to be a primary factor in clinical and MRI improvement.

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Ultrastructural changes of compressed lumbar ventral nerve roots following decompression. [El-Barrany WG](#), [Hamdy RM](#), [Al-Hayani AA](#), [Jalalah SM](#), [Al-Sayyad MJ](#).

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OBJECTIVE: To study whether there will be a permanent lumbar nerve root scarring or degeneration secondary to continuous compression followed by decompression on the nerve roots, which can account for postlaminectomy leg weakness or back pain. **METHODS:** The study was performed at the Department of Anatomy, Faculty of Medicine, King Abdul-Aziz University, Jeddah, Kingdom of Saudi Arabia during 2003-2005. Twenty-six adult male New Zealand rabbits were used in the present study. The ventral roots of the left fourth lumbar nerve were clamped for 2 weeks then decompression was allowed by removal of the clips. The left ventral roots of the fourth lumbar nerve were excised for electron microscopic study. **RESULTS:** One week after nerve root decompression, the ventral root peripheral to the site of compression showed signs of Wallerian degeneration together with signs of regeneration. Schwann cells and myelinated nerve fibers showed severe degenerative changes. Two weeks after decompression, the endoneurium of the ventral root showed extensive edema with an increase in the regenerating myelinated and unmyelinated nerve fibers, and fibroblasts proliferation. Three weeks after decompression, the endoneurium showed an increase in the regenerating myelinated and unmyelinated nerve fibers with diminution of the endoneurial edema, and number of macrophages and an increase in collagen fibrils. Five and 6 weeks after decompression, the endoneurium showed marked diminution of the edema, macrophages, mast cells and fibroblasts. The endoneurium was filled of myelinated and unmyelinated nerve fibers and collagen fibrils. **CONCLUSION:** Decompression of the compressed roots of a spinal nerve is followed by regeneration of the nerve fibers and nerve recovery without endoneurial scarring.

Interspinous Process Decompression With the X-STOP Device for Lumbar Spinal Stenosis: A 4-Year Follow-Up Study. [Kondrashov DG](#), [Hannibal M](#), [Hsu KY](#), [Zucherman JF](#). St. Mary's Spine Center, One Shrader Street, Suite 450, San Francisco, CA 94117.

X-STOP is the first interspinous process decompression device that was shown to be superior to nonoperative therapy in patients with neurogenic intermittent claudication secondary to spinal stenosis in the multicenter randomized study at 1 and 2 years. We present 4-year follow-up data on the X-STOP patients. Patient records were screened to identify potentially eligible subjects who underwent X-STOP implantation as part of the FDA clinical trial. The inclusion criteria for the trial were age of at least 50 years, leg, buttock, or groin pain with or without back pain relieved during flexion, being able to walk at least 50 feet and sit for at least 50 minutes. The exclusion criteria were fixed motor deficit, cauda equina syndrome, previous lumbar surgery or spondylolisthesis greater than grade I at the affected level. Eighteen X-STOP subjects participated in the study. The average follow-up was 51 months and the average age was 67 years. Twelve patients had the X-STOP implanted at either L3-4 or L4-5 levels. Six patients had the X-STOP implanted at both L3-4 and L4-5 levels. Six patients had a grade I spondylolisthesis. The mean preoperative Oswestry score was 45. The mean postoperative Oswestry score was 15. The mean improvement score was 29. Using a 15-point improvement from baseline Oswestry Disability Index score as a success criterion, 14 out of 18 patients (78%) had successful outcomes. Our results have demonstrated that the success rate in the X-STOP interspinous process decompression group was 78% at an average of 4.2 years postoperatively and are consistent with 2-year results reported by Zucherman et al previously and those reported by Lee et al. Our results suggest that intermediate-term outcomes of X-STOP surgery are stable over time as measured by the Oswestry Disability Index.

Vertebral Axial Decompression Therapy For Pain Associated With Herniated Or Degenerated Discs Or Facet Syndrome: An Outcome Study.

The Effects Of Vertebral Axial Decompression On Sensory Nerve Dysfunction In Patients With Low Back Pain And Radiculopathy.

Canadian Journal of Clinical Medicine (pressure to a negative 150Mm Hg., allowing
Effects Of Vertebral Axial Decompression On Intradiscal Pressure.

- Journal of Neurosurgery

Vax-D stands for **V**ertebral **A**xial **D**ecompression. It is a non-invasive treatment for patients suffering from the painful and disabling effects of bulging discs, herniated discs and degenerative disc disease. Vax-D is designed to relieve pressure on structures that cause low back pain. Vax-D is safe and effective without any of the risks associated with surgery, anesthesia, injections or drugs.

The Vax-D unit creates a vacuum affect in the disc.

This accomplishes 3 tasks:

- draws the jelly nucleus back to its proper place
- repair of the fibrous outer layer
- bringing nutrients to the disc to allow it to rehydrate

CBS news estimated that out of 500,000 spinal surgeries performed each year in the United States, over 80,000 are unnecessary.

Spinal surgery ranks 3rd among all surgical procedures, yet statistics show the majority to be less than 31% successful.

**50 ADDITIONAL DECOMPRESSION RESEARCH ARTICLES
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Long-term back pain after a single-level discectomy for radiculopathy: incidence and health care cost analysis

Clinical article

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Object. The most common spinal procedure performed in the US is lumbar discectomy for disc herniation. Long-term disc degeneration and height loss occur in many patients after lumbar discectomy. The incidence of mechanical back pain following discectomy varies widely in the literature, and its associated health care costs are unknown. The authors set out to determine the incidence of and the health care costs associated with mechanical back pain attributed to segmental degeneration or instability at the level of a prior discectomy performed at their institution.

Methods. The authors retrospectively reviewed the data for 111 patients who underwent primary, single-level lumbar hemilaminotomy and discectomy for radiculopathy. All diagnostic modalities, conservative therapies, and operative treatments used for the management of postdiscectomy back pain were recorded. Institutional billing and accounting records were reviewed to determine the billed costs of all diagnostic and therapeutic measures.

Results. At a mean follow-up of 37.3 months after primary discectomy, 75 patients (68%) experienced minimal to no back pain, 26 (23%) had moderate back pain requiring conservative treatment only, and 10 (9%) suffered severe back pain that required a subsequent fusion surgery at the site of the primary discectomy. The mean cost per patient for conservative treatment alone was \$4696. The mean cost per patient for operative treatment was \$42,554. The estimated cost of treatment for mechanical back pain associated with postoperative same-level degeneration or instability was \$493,383 per 100 cases of first-time, single-level lumbar discectomy (\$4934 per primary discectomy).

Conclusions. Postoperative mechanical back pain associated with same-level degeneration is not uncommon in patients undergoing single-level lumbar discectomy and is associated with substantial health care costs.
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KEY WORDS • lumbar discectomy • back pain • radiculopathy • health care costs

THE notion of a herniated disc fragment causing neural compression in the lumbar spinal canal was first reported by Mixter and Barr in 1934.¹⁵ Today, lumbar discectomy is the most commonly performed spinal procedure in the US, with ~ 300,000 cases each year.^{2,7} Multiple studies have revealed that lumbar discectomy improves pain, physical function, and disability in the majority of patients;^{12,16,19–21} however, 10–30% of patients may experience long-term back pain following primary discectomy for radiculopathy.^{3–5}

Progressive disc degeneration and height loss at the level of discectomy occur in most patients and, in fact, contribute to postdiscectomy mechanical back pain in a subset of them.^{1,13,22} Yorimitsu et al.²² have found a 25% loss of disc height in most patients 1 year after lumbar discectomy, a phenomenon associated with worsened back pain. Barth et al.¹ have reported a significant in-

crease in endplate degeneration and disc dehydration following discectomy, phenomena that were associated with worsened back pain in that study.

Conservative therapy for postdiscectomy back pain includes epidural steroid injection, nerve or facet blocks, radiofrequency ablation, and/or physical therapy. For patients whose condition is refractory to these measures or who demonstrate segmental instability, fusion may be required. While the incidence of postdiscectomy fusion remains unclear, multiple studies have documented the successful treatment of refractory postdiscectomy back pain with spinal fusion.^{8,11,17}

The incidence of mechanical back pain following discectomy varies widely in the literature, and its associated health care costs are unknown; therefore, we set out to identify the incidence of and the health care costs associated with mechanical back pain attributed to segmental degeneration or instability at the level of a prior discectomy performed at our institution.

Abbreviation used in this paper: IQR = interquartile range.

Methods

Data Collection

Subsequent to obtaining approval from The Johns Hopkins Institutional Review Board, we reviewed all single-level, first-time lumbar discectomies performed by a single spine neurosurgeon (D.M.L.) between January 1, 1997, and January 1, 2007. All of these patients underwent lumbar discectomy only if they had 1) preoperative imaging clearly demonstrating lumbar disc herniation, 2) radicular symptoms ascribable to a disc level, and 3) symptoms refractory to at least 6 weeks of conservative treatment. Patients undergoing bilateral laminectomy or concomitant fusion or presenting with additional spinal pathologies were excluded from our analysis. Patient's lost to follow-up prior to the first clinic visit at 1 month postoperatively were also excluded from the study.

Medical records were reviewed and patient demographics, presenting symptoms, preoperative radiographic findings, operative variables, perioperative morbidity, duration of hospitalization, and clinical outcomes were recorded. For patients who experienced postdiscectomy mechanical back pain, all diagnostic studies (MR imaging, CT, radiography, electromyography, or discography), conservative treatments (epidural steroid injections, nerve blocks, radiofrequency nerve ablation, or physical therapy), and details of subsequent surgeries for back pain were noted. It was not our aim to assess symptomatic recurrent disc herniation, but rather the back pain associated with same-level disc degeneration, spondylolisthesis, or instability.

To assess the health care costs associated with the treatment of mechanical back pain following single-level discectomy, institutional billing and accounting records were reviewed to determine the billed costs of all diagnostic and therapeutic measures used for patients experiencing recurrent mechanical back pain. Such measures included the diagnostic and conservative treatments listed above, hospitalization for subsequent same-level fusion, and any physical therapy required after subsequent fusion surgery. For the purposes of this study, "health care cost" was defined as the total amount billed for all procedures and health care services related to the management of postdiscectomy mechanical back pain.

Case Definition

Postdiscectomy back pain was defined as same-segment, degenerative, disc-associated axial back pain that was mechanical in nature and demonstrated both decreased disc height and decreased T2 signal intensity from the time of primary discectomy. Patients were stratified into 3 categories according to their postdiscectomy back pain status: 1) minimal to none, 2) moderate, or 3) severe. Minimal to none refers to no back pain postoperatively or to back pain that was amenable to narcotics and/or antiinflammatory drugs. Moderate describes back pain that required and was successfully managed with conservative treatments such as nerve blocks, facet blocks, and/or epidural steroid injections. Severe indicates back pain that was refractory to conservative treatments and therefore required surgical management.

Primary Discectomy Technique and Postoperative Management

Patients underwent surgical intervention while in the prone position under general anesthesia. Preincision plain radiographs were obtained to identify the correct spinal level. A midline skin incision was made, followed by unilateral subperiosteal dissection of the lumbar paraspinal muscles for exposure of the laminae. A portion of the caudal aspect of the superior lamina and the rostral aspect of the inferior lamina were removed, followed by a partial medial facetectomy to unroof the lateral recess if needed. The herniated disc was removed, and a nerve hook was used to free any migrated fragments. In cases of minimal annular defect, disc curettage was not performed. In cases with a sizable annular defect, however, a subannular discectomy with curettage was undertaken. The compressed nerve root was always examined along its course to the foramen inferior to the pedicle and, if necessary, a foraminotomy was performed prior to closure.

Routine postoperative follow-up consisted of evaluation at 1, 3, 6, and 12 months and annually thereafter. Patients experiencing mechanical axial back pain that was believed to interfere with their quality of life underwent flexion and extension radiography to rule out overt instability and were started on various conservative treatment modalities. Those continuing to experience mechanical back pain beyond 1 year postoperatively routinely underwent MR imaging to assess for disc degeneration, spondylolisthesis, or facet and ligamentous hypertrophy. If severe back pain remained refractory to nonsurgical treatment in the presence of radiographically confirmed degeneration or instability, a fusion procedure was then considered. Patients who experienced continual back pain without radiographic signs of segmental instability or degeneration of the prior discectomy segment were treated with prolonged conservative (nonsurgical) therapy.

Results

Patient Population

One hundred eleven consecutive patients meeting the inclusion criteria underwent first-time, single-level lumbar discectomy over the reviewed period. The average age was 52 years (range 17–89 years), and 64 patients (58%) were male. Patient symptoms before primary discectomy consisted of radicular pain (90%), mild motor weakness (49%), numbness (46%), and lower extremity paresthesias (19%). Fifty-six patients (50%) had left-sided symptoms and 55 (50%) had right-sided symptoms. The level of disc herniation was L1–2 in 4 patients (4%), L2–3 in 7 (6%), L3–4 in 16 (14%), L4–5 in 47 (42%), and L5–S1 in 37 (33%). The median duration of symptoms prior to surgery was 7 months (IQR 1–18 months; Table 1).

Perioperative Outcomes

No perioperative death was associated with any of the 111 first-time discectomies. The median duration of hospitalization was 2 days (IQR 1–5 days). Perioperative complications included deep vein thrombosis (1 case [0.9%]) and surgical site infection (1 case [0.9%]). One

TABLE 1: Summary of characteristics in 111 patients who underwent discectomy

Parameter	No. (%)		
	Minimal to No Back Pain	Moderate Back Pain	Severe Back Pain
no. of patients	75	26	10
age in yrs	51	55	57
male sex	42 (56)	17 (65)	5 (50)
duration of symptoms prediscectomy (mos)	16	18	33
level of discectomy			
L1–2	4 (6)	0 (0)	0 (0)
L2–3	6 (8)	1 (4)	0 (0)
L3–4	10 (13)	4 (15)	2 (20)
L4–5	31 (41)	11 (42)	5 (50)
L5–S1	24 (32)	10 (39)	3 (30)
same-level degenerative changes prediscectomy	39 (52)	14 (54)	5 (50)
time to recurrent pain postdiscectomy (mos)	—	9	7
time to fusion postdiscectomy (mos)	—	—	19.6

hundred nine patients (98%) were discharged home following surgery, whereas 2 (2%) required inpatient rehabilitation because of persistent preoperative motor weakness.

Incidence and Management of Postoperative Mechanical Back Pain

The mean duration of follow-up after the primary discectomy procedure was 37.3 months (range 1 month–12.2 years). Seventy-five percent of patients were in active follow-up at 3 months postoperatively, 68% at 6 months, and 63% at 1 year. At the last follow-up, 75 patients (68%) had minimal to no back pain, 26 (23%) had moderate back pain requiring conservative therapy, and 10 (9%) had severe back pain that required a subsequent fusion surgery at the site of the primary discectomy because of segmental instability (Table 2). Radiographically identified disc degeneration was present in all 36 patients with back pain requiring conservative or operative management. Additionally, posterior ligamentous hypertrophy and vertebral hypermobility were found in 22 (61%) and 5 (14%) cases, respectively. A review of radiographic images obtained before the primary discectomy revealed that 19 patients (53%) who would later experience clinically significant postdiscectomy back pain actually had signs of same-level degenerative changes preoperatively. Similarly, 39 patients (52%) who did not experience postdiscectomy back pain had signs of same-level degenerative disease preoperatively. The median time from the initial discectomy to the subsequent fusion procedure was 14 months (IQR 11–19 months). The fusion procedures consisted of 3 in situ fusions (30%), 5 transpedicular instrumented fusions (50%), and 2 transforaminal lumbar interbody fusions (20%).

Health Care Costs Associated With Recurrent Back Pain

The total cost associated with the diagnosis and management of postoperative mechanical back pain for the

36 patients in this study was \$547,655: diagnostic testing \$109,798; conservative therapy \$120,881; and subsequent fusion surgery \$316,976. The mean cost per patient treated with conservative therapy alone was \$4696, whereas the mean cost per patient requiring operative treatment was \$42,554 (Table 3). In this study, the estimated cost for patients with mechanical back pain was \$493,383 per 100 cases of first-time, single-level lumbar discectomy (\$4934 per primary discectomy).

Discussion

In our experience with 111 patients undergoing primary single-level lumbar discectomy, the majority of patients experienced minimal to no back pain by 3 years postoperatively. The patients who had clinically significant low-back pain included 26 (23%) who responded to conservative therapy and 10 (9%) whose symptoms were refractory to conservative treatment and required spinal fusion; hence, the majority of patients with clinically significant back pain responded to conservative therapy alone. While 25% of patients in the study were lost to follow-up between 1 and 3 months postoperatively, this rate of attrition is not uncommon following a single-level discectomy procedure. We believe the majority, if not all, of these patients experienced complete resolution of their

TABLE 2: Outcome after first-time single-level discectomy for lumbar disc herniation and radiculopathy

Outcomes	Value
patients w/ minimal to no back pain (%)	75 (68)
patients w/ moderate back pain (%)	26 (23)
patients w/ severe back pain (%)	10 (9)
median no. of mos from discectomy to subsequent fusion (IQR)	14 (11–19)

Long-term back pain following single-level discectomy

TABLE 3: Health care costs associated with the management of back pain attributed to segmental instability or degenerative disc disease at the level of prior discectomy in 36 patients*

Therapy Required	No. of Patients	Mean Cost/Patient Treated for Recurrent Back Pain			Total Cost
		Diagnostic Testing†	Conservative Therapies‡	Op Treatment§	
conservative therapy alone	26	\$2,291	\$2,405	\$0	\$4,696
op treatment	10	\$5,022	\$5,834	\$31,698	\$42,554

* All monetary values expressed in US dollars.

† Includes MR imaging, CT, radiography, and discography.

‡ Includes physical therapy and injections.

§ Includes the cost of surgery, all in-hospital charges, and postoperative rehabilitation.

preoperative symptoms and therefore terminated their postoperative clinical care.

The diagnosis and management of postdiscectomy back pain was associated with substantial health care costs. The total cost associated with the diagnosis and management of the 36 cases of postdiscectomy back pain in our series was \$547,655. This total cost suggests an additional estimated \$493,383 per 100 cases of primary single-level discectomy was required for postdiscectomy mechanical back pain at our institution. For the purposes of this study, cost was defined as the total amount billed, rather than collected, for all procedures related to postdiscectomy back pain. The percent collected varies as a function of hospitals and individual patients, but is always less than the amount billed. As a result, the total health care cost paid was probably less than the total amount billed per patient with postdiscectomy back pain. Note that the indirect socioeconomic costs associated with missed work and the cost of outpatient pain medications were not assessed in our analysis, suggesting that the overall cost per patient with postdiscectomy back pain may be higher than the hospital costs estimated here. Nevertheless, our results suggest that postdiscectomy back pain is not uncommon and is associated with significant health care costs in affected patients.

A principle etiology of disc-associated mechanical back pain is disc degeneration (Fig. 1). In the present study, disc degeneration was radiographically demonstrated in all 36 patients with clinically significant back pain. Yorimitsu et al.²² have shown a $\geq 25\%$ loss of disc height in a majority of patients following lumbar discectomy, a phenomenon associated with worsening back pain. Barth et al.¹ have reported a significant increase in endplate degeneration and disc dehydration following discectomy, phenomena also associated with worsening back pain. Data from both of these studies indirectly suggest that minimal endplate injury and subannular disc removal should be the goal of discectomy for radiculopathy.

Although the present analysis is based solely on the experience of a single surgeon at one institution, our results fall within the expected norm and can be considered representative. Consistent with the findings described here, a 5% incidence of postdiscectomy back pain requiring operative treatment has been reported by Ruetten et al.¹⁸ Other studies have documented postdiscectomy back pain in 10–30% of patients by using subjective pain

scales and mailed questionnaires.^{3–6,9,10,14,20} Because surgical techniques differ and pain assessment scales vary, the reported incidence of postdiscectomy back pain is difficult to objectively compare. While the outcomes following primary single-level discectomy in the present study are consistent with prior reports, it remains unclear how different management strategies may affect costs associated with postdiscectomy back pain. In our practice, we attempt to conservatively treat all patients experiencing postdiscectomy back pain, prior to imaging. Such treatment includes 2 days of bed rest, nonsteroidal antiinflammatory medications, and physical therapy. Radiological studies are pursued only after these acute measures have failed. Even in cases with a radiographically confirmed etiology for back pain, a prolonged course (> 3 months) of conservative therapy will be attempted in the absence of acutely worsening motor deficits, prior to operative treat-



FIG. 1. A: Computed tomography scan showing extensive L3–4 disc degeneration 9 months after primary discectomy. **B:** Plain radiograph showing the same region after spinal stabilization using pedicle screws with interbody fusion at L3–4. This patient originally underwent L3–4 microdiscectomy after presenting with right lower extremity radiculopathy and a large herniated L3–4 disc fragment. The patient fared well postoperatively but returned months later with severe mechanical back pain. Three months of conservative therapy failed, and the patient was eventually offered an instrumented fusion. The patient experienced a significant reduction in low-back pain 9 months after fusion.

ment. Practices that are more aggressive in pursuing operative treatment may incur even greater health care costs associated with the management of postdiscectomy back pain compared with those reported in this study.

Our experience with primary single-level lumbar discectomy highlights the importance of postdiscectomy back pain as a significant contributor to unsatisfactory patient outcomes and excessive health care costs. In an attempt to reduce the costs associated with postdiscectomy back pain, the application of prolonged conservative therapy may be prudent.

Conclusions

Postoperative mechanical back pain associated with same-level degeneration is not uncommon in patients undergoing single-level lumbar discectomy. The majority of postdiscectomy back pain can be successfully managed with conservative treatments. Nonetheless, the diagnosis and treatment of postdiscectomy back pain is associated with substantial health care costs.

Disclosure

Dr. McGirt is a consultant for Intrinsic Therapeutics, Inc.

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Percutaneous Discectomy

Department of Labor and Industries
Office of the Medical Director

February 24, 2004

Percutaneous Discectomy

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Percutaneous Discectomy

Introduction

A herniated intervertebral lumbar disc results from a protrusion of the nucleus pulposus. A ruptured annulus fibrosis causes an extruded disc while an intact but stretched annulus fibrosis results in a contained disc prolapse. This may compress one or more nerve roots causing pain along the sciatic nerve. (Boult 2000)

Percutaneous discectomy is a class of minimally invasive surgical procedures that treat contained, herniated discs. One theory for improvement from percutaneous discectomy suggests that removal of disc material reduces the intradiscal pressure so that the herniated segment can fall back into place. Another proposed mechanism is that removing disc material may prevent release of chemical mediators that directly injure the nerve root. (Delamarter 1995)

Specific procedures within the class include manual percutaneous lumbar discectomy, automated percutaneous lumbar discectomy (APLD), laser discectomy, and nucleoplasty. Manual discectomy removes disc material with forceps whereas APLD removes disc material with a suction cutting probe. Laser discectomy uses laser energy transformed into heat to vaporize disc tissue. Finally, Nucleoplasty uses radiofrequency energy to break molecular bonds within tissue, creating small channels in the disc.

Percutaneous discectomy is generally indicated for patients with contained disc herniations or prolapse resulting in radicular pain equal to or greater than back pain. Patients should have attempted conservative treatment. MRI, CT, CT myelogram, or discography may confirm disc pathology.

General contraindications for percutaneous discectomy are free disc fragment, bone spur impingement on the nerve root, previous surgery with scar tissue nerve entrapment, spondylolisthesis, and bony spinal stenosis. (Caspar 1995) (Choy 1998)

Advocates of percutaneous approach cite a shorter stay in the hospital, decreased epidural scar formation, avoidance of general anesthesia, preservation of spinal stability, and decreased cost as advantages. (Delamarter 1995)

This review includes prospective studies with more than 20 subjects and published in English after 1993.

Manual Percutaneous Lumbar Discectomy

Published Studies

I. Randomized Trials

- a. Hermantin compared arthroscopic posterolateral discectomy to open discectomy and laminotomy with regard to low back pain and radicular symptoms, objective physical findings, duration of disability, and medication use. (Hermantin 1999)

Arthroscopic discectomy was performed with an oval 5 by 8 mm cannula that fit within the boundaries of the triangular working zone between the traversing and exiting nerve roots. The herniated disc fragments are pulled back into the intervertebral disc space and then are withdrawn. While the arthroscopic discectomy was outpatient, the laminotomy/discectomy required one night hospital stay.

Patients were considered to have satisfactory outcomes if they were rated as excellent or good.

- Excellent - radicular symptoms ceased, negative tension sign, return to normal activities, patient expressed satisfaction
- Good - excellent results, but with residual back pain and modified occupation

Follow-up occurred at 2 weeks, 3 months, 6 months, 1 year, and 2 years.

Study Population: The study randomized 60 patients (mean age 39.5 years) to open laminotomy and discectomy or video-assisted arthroscopic microdiscectomy.

	Number of patients	
	open laminotomy and discectomy	video-assisted arthroscopic microdiscectomy
L2-L3		1
L3-L4	1	6
L4-L5	23	19
L5-S1	6	4
Reflex abnormalities	9	12
Sensory deficit	28	26
Motor weakness	26	24

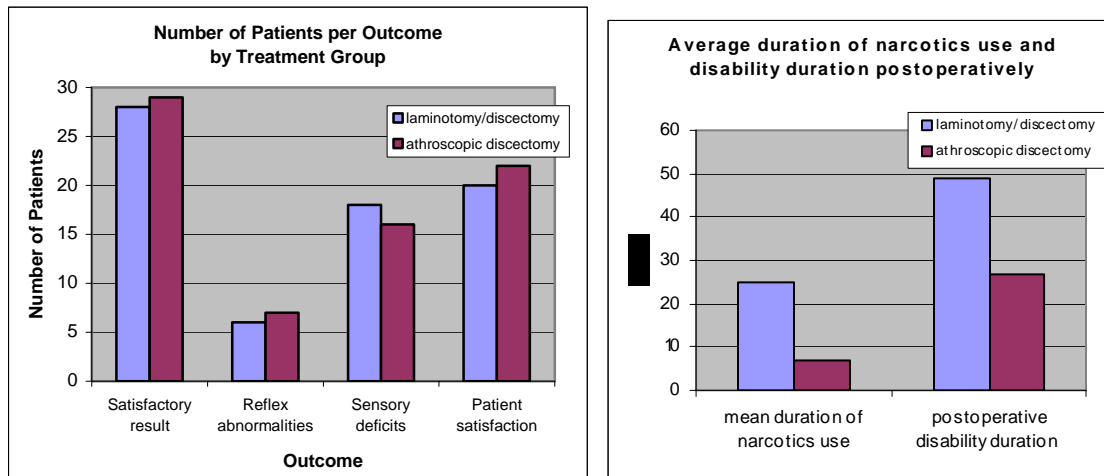
The study included patients with more pain in the lower extremities than in the back that failed 14 weeks of nonoperative measures. They had a single disc herniation that did not exceed one-half of the diameter of the spinal canal. There was an absence of ventral or lateral osseous or ligamentous stenosis. Patient had positive tension signs and had no previous operation on the low back.

Manual Percutaneous Lumbar Discectomy (MPLD)

The study excluded patients due to central or lateral stenosis, severe degenerative narrowing of the disc space, global bulging of the intervertebral disc associated with central or lateral stenosis, sequestered herniation that had migrated, large central or extraligamentous herniation between L5-S1, or litigation or workers' compensation claim.

Results: The mean duration of follow-up was 31 months for the open discectomy group and 32 months for the arthroscopic discectomy group.

Mean postoperative pain score was 1.9 points for the open discectomy group and 1.2 for the arthroscopic group.



At latest follow-up, 6 open discectomy patients reported occasional use of codeine derivatives for control of LBP or lower extremity pain. One patient experienced procedure failure.

One arthroscopic discectomy patient required additional surgery.

Conclusion: Although the number of patients who had a satisfactory outcome was similar in the two groups, the rate of postoperative morbidity was lower in the patients who had the minimally invasive surgery.

- b. Mayer compared 40 patients randomly assigned to one of 2 groups of 20 patients treated with percutaneous discectomy (PLD) or by microdiscectomy (micro). (Mayer 1993)

Patient symptoms were transformed into a 10-point scoring system modified from the Suezawa and Schreiber system. Patients were followed for two years.

Manual Percutaneous Lumbar Discectomy (MPLD)

Study Population:

Patient Demographic		
	PLD	Micro
Number of patients	20	20
Average age	39.8 years	42.7 years
Average duration of symptoms	6.9 months	7.3 months
Average preoperative disability	10.4 weeks	10.4 weeks
Preoperative sensory disturbances	13 patients	16 patients
L4-L5	18	19
L3-L4	1	1
L3-L4, L2-L3	1	0
Time of procedure	40.7 minutes	58.2 minutes
Amount of disc material removed	4.3 g	12.8 g

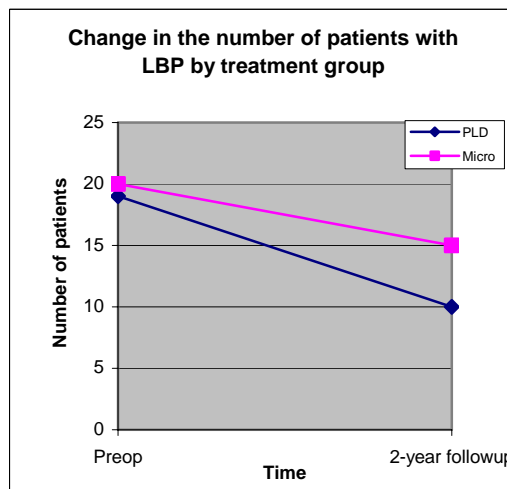
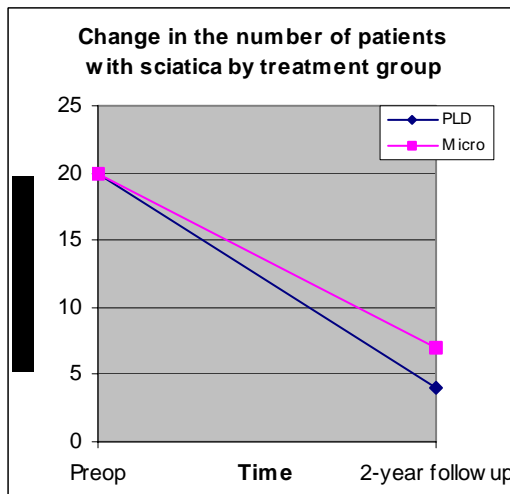
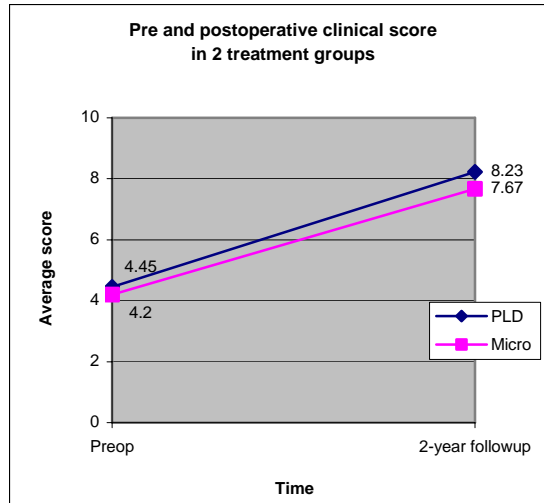
The study included patients with discogenic nerve root compression. Patients showed radicular symptoms such as straight-leg raising test, sciatica, sensory disturbances, mild motor weakness, and reflex differences. MRI, CT, discography, post-discography CT, or myelography showed a contained herniation or small, noncontained herniation. A small, noncontained herniation was defined as extrusion of nucleus pulposus under the posterior longitudinal ligament and occupying not more than one-third of the sagittal diameter of the spinal canal.

Patients were excluded due to severe motor deficits, conus or cauda equina syndrome, progressing neurological symptoms, segmental instability, previous surgery, psychogenic aggravation, workers' compensation, large noncontained herniation, sequestered disc, stenosis, or spondylolisthesis.

Results: All 20 PLD patients were satisfied with their procedures compared to 17 satisfied microdiscectomy patients.

Outcomes by Treatment Group		
	PLD	Micro
Excellent	11 patients	7 patients
Good	3 patients	6 patients
Moderate	3 patients	4 patients
Bad	--	3 patients
Mean duration of postop disability	7.7 weeks	22.9 weeks
Return to work	19 patients	13 patients

Manual Percutaneous Lumbar Discectomy (MPLD)



Conclusion: The authors conclude that the clinical results are comparable. The results of the study justify percutaneous discectomy as a surgical alternative for patients with “contained” or slight subligamentous lumbar disc herniations.

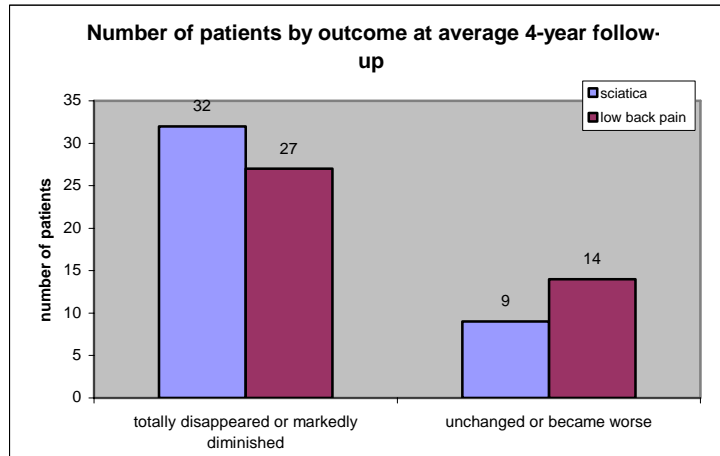
II. Case Series

- Kotilainen evaluated 41 patients, which represented 91% of the original study population. The patients’ mean age was 49 years. 17 patients (55%) were employed in light work and 14 patients (45%) in heavy work. (Kotilainen 1998)

Patients were evaluated with a 100mm VAS and examined for the presence of segmental instability of the lumbar spine using 3 criteria: instability catch, painful catch, and apprehension. The mean postoperative follow-up time was 5 years.

Manual Percutaneous Lumbar Discectomy (MPLD)

Results: The mean VAS decreased from 83 to 36.

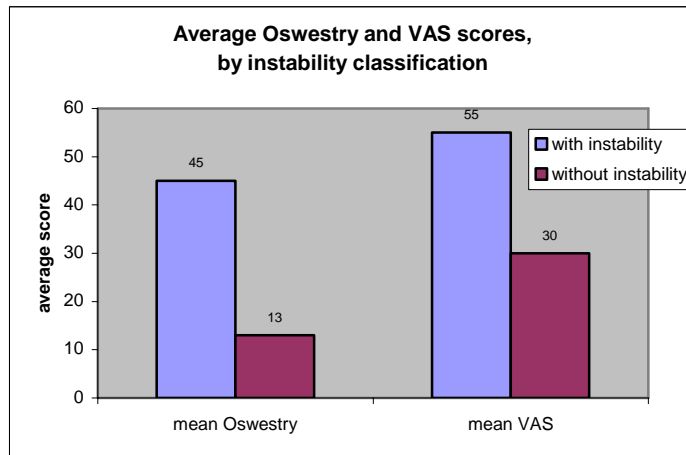


Various signs and symptoms of segmental instability were detected in 10 (24%) patients. Five of these patients did not show instability preoperatively.

	Number of patients	Percent of patients
Instability Catch	8	20%
Painful Catch	6	15%
Apprehension	9	22%

Of the 29 patients who were working at follow-up, 13 patients managed their work well. 2 patients were on sick leave due to back pain. 5 patients were retired because of the back and 5 patients retired due to other reasons.

Postoperative outcome was evaluated separately for patients with and without segmental instability. Patients with instability suffered more often from low back pain and sciatica than did those without instability.



Manual Percutaneous Lumbar Discectomy (MPLD)

During the follow-up period, 6 (15%) patients required reoperation. Recurrent disc herniation was detected in 3 (7%) patients. Mean duration between the original operation and reoperation was 2.5 years.

Conclusion: Nucleotomy is an effective and safe alternative to open disc surgery in the treatment of patients with a small prolapse or a small protrusion who have not responded to conservative treatment. The subgroup of patients with segmental instability experienced inferior outcomes.

- b. Lin evaluated 35 cases (mean age 35.5 years) with fourth or fifth lumbar or first sacral radiculopathy unresponsive to 6 weeks of unsuccessful therapy. Image studies showed a herniated nucleus pulposus. Patients were excluded due to moderate or severe spinal stenosis, lateral recess stenosis, degenerative facet disease, far lateral herniation, free fragment, or previous lumbar spinal surgery. (Lin 1994)

The study used the following grading system to monitor outcomes. The average follow-up was 9.3 months.

Grading system

	Activity level	Pain	Analgesic use	Work Status
1 points	Severely limited	Continuous	Continuous	Unemployed
2 points	Use of cane or assistance	Frequent	Frequent	Modified
3 points	Minimally limited	Occasional	Occasional	Original
4 points	Full activity	None	None	

The treatment was considered successful if:

Original score	Functional score
<10	>10 and increase > 3
>=10	Increase >3

Failure was defined as requiring an additional procedure or patient dissatisfaction.

The mean duration of symptoms was 15.6 months and the average time out of work before the operation was 3.2 months. The procedure removed 4 to 7 g of disc material.

Results:

Number (%) of Patients with Successful Outcome by Disc Level and Follow-up

Level	2 month	6 month
L3-L4	1/1 (100%)	1/1 (100%)
L4-L5	25/30 (83%)	22/29 (76%)
L5-S1	3/4 (75%)	3/4 (75%)
Total	29/35 (83%)	26/34 (76%)

One case of discitis developed.

Manual Percutaneous Lumbar Discectomy (MPLD)

Conclusion: The authors state that the study provides an objective means of selecting cases and evaluating surgical results, which makes the use of the procedure predictable.

- c. Mochida observed 107 patients and analyzed data from 85 patients (average age 26.3 years) with unilateral involvement of the lower extremity induced by one level compression to the spinal nerve root. The patients attempted conservative therapy for more than 6 months. The study excluded patients if CT after discography and MRI showed perforation of the posterior longitudinal ligament or stenosis. (Mochida 1993)

Patients were monitored for a minimum of 2 years with the Japanese Orthopaedic Association (JOA) score for low back pain. Scores higher than 12 points were considered successful.

	LBP	Leg Pain and/or Tingling	Gait	Straight leg raising test	Sensory disturbance	Motor disturbance
0 pts	Frequent or continuous severe		Unable to walk farther than 100 m because of pain, tingling, or muscle weakness	Less than 30 degrees	Marked	
1 pts	Frequent mild or occasional severe		Unable to walk farther than 500 m because of pain, tingling, or muscle weakness	30 to 70 degrees	Slight	
2 pts	Occasional mild		Walk farther than 500 m although it results in pain, tingling, or muscle weakness	Normal	Normal	
3 pts	None		Normal			

Results: At average 2.4-year follow-up, 54 subjects (64%) had successful results. Of the 31 unsuccessful patients, 22 were retreated with open surgery.

Subgroup analysis showed that 5 of 7 patients older than 40 had unsuccessful results. Of the 78 patients younger than 40, 26 had unsuccessful results. Grade 3 on manual muscle testing in the innervated muscles also showed less successful outcomes.

Conclusion: The researchers recommend excluding patients older than 40 because of degenerative change of the bone structure, which is likely to compress the spinal nerve root.

Automated percutaneous lumbar discectomy (APLD)

In 1985, Automated Percutaneous Lumbar Discectomy (APLD) was developed. APLD is performed with a pneumatically driven, suction-cutting probe in a cannula with 2.8 mm outer diameter. The automated probe or rongeur is passed anterolateral to the actual herniation and comes to rest in the center of the disc. Most of the disc removal occurs 1 cm anterior to the herniation. APLD generally removes 2 to 3 g of disc material to reduce intradiscal pressure and decompress the nerve root compression. (Delamarter 1995) (Revel 1993) (Sakou 1993)

Predictive Factors

Delamarter reviewed the MRI studies of 30 patients (mean age 34 years) before and after APLD to identify features that might predict outcome. Preoperative studies were reviewed retrospectively and average follow-up was 14 months. The study defined success nearly complete pain resolution, no pain medication, and return to work without restrictions.

Imaging studies 4 to 6 weeks after the operation for 14 successful patients did not show any changes in disc morphology. Studies at mean 8 months showed that 3 patients had a reduction of the size of the herniated segment. However, Delamarter found no association between preoperative size or location of the herniated disc and a successful clinical outcome. They conclude that it is difficult to predict the clinical outcome of a percutaneous discectomy. (Delamarter 1995)

Dullerud conducted a retrospective review of 142 patients to assess predictive clinical factors. The study used broader inclusion criteria allowing patients with predominant LBP, bulging disks with diffuse posterior extension of the disk margin beyond the adjacent vertebral endplates, or concomitant spinal stenosis.

Patients with normal or slightly narrowed disc space experienced better results compared to patients with a larger degree of disc space narrowing. Results were also better at the 5th disc level than at the 4th disc level. (Dullerud 1995)

Published Studies

I. Randomized trials of APLD and chemonucleolysis

- a. Revel randomized patients with sciatica caused by a disc herniation to undergo either APLD or chemonucleolysis (CN). (Revel 1993)

The study measured outcomes with a 100 mm VAS to measure sciatica and LBP, a straight leg test, the Schober test, neurologic status, self-assessment, disc height, and herniation size.

Automated Percutaneous Lumbar Discectomy (APLD)

The principal outcome was overall assessment of the patient 6 months after treatment. Nil and moderate results, withdrawal because of surgery, or loss to follow-up were considered failures.

Follow-up occurred at the day of discharge, 1 month, 3 months, and 6 months.

Revel calculated that 80 patients in each treatment group would permit observation of a 20% difference in outcome.

Study Population: The study included and excluded patients based on the following criteria.

Inclusion	Exclusion
<ul style="list-style-type: none"> • Unresponsive to conservative medical therapy (average 20 weeks) • CT scan, MRI, or myelography demonstrated herniation at only one level • Chief symptom of sciatica caused by herniation 	<ul style="list-style-type: none"> • Prior lumbar surgery or chymopapain injection • Severe neurologic problems • Lateral recess or central spinal stenosis • Disc migration of more than 5 mm away from vertebral endplates • Large herniation, calcified herniation, vacuum disc, or disc height less than 5 mm

Of the 164 eligible patients initially randomized, 19 subjects were excluded just before the procedure and 5 treated patients were excluded after first follow-up. The reduced number did not affect statistical power.

The trial included 72 CN (mean age 40 years) and 69 APLD (mean age 37 years) subjects. 43% of CN and 26% of APLD were considered sedentary subjects, and the disc appeared degenerated more often in the CN group (92%) than in the APLD group (76%).

15% of CN and 20% of APLD subjects received workers' compensation.

The study considered the 32 patients who withdrew during trial as therapeutic failures.

	CN	APLD
open laminectomy	5	23
technical failure	0	2
lost to follow-up	2	0

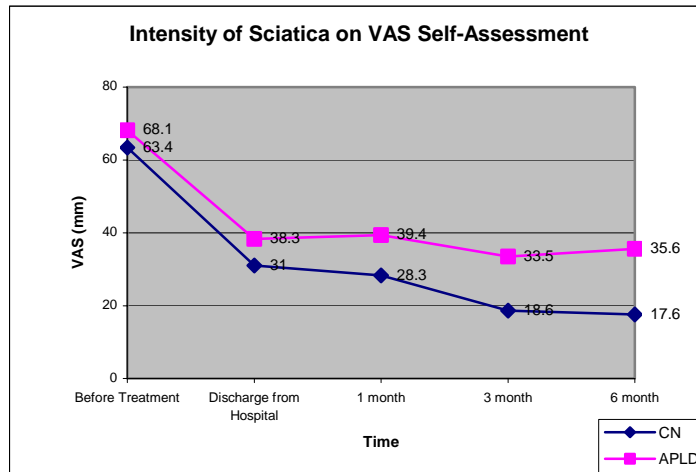
Results:

	CN	APLD
6 months	44/72 (61%)	30/69 (44%)
1 year	48/58 (83%)	25/41 (61%)

Automated Percutaneous Lumbar Discectomy (APLD)

Overall assessment of success rate at 6 months

	CN	APLD
Physician opinion	77%	83%
Patient opinion	69%	68%



Among the 52 CN and 41 APLD subjects employed at study entry, the duration of absence from work was 107 days in the CN group and 93 days in the APLD group.

Percent of patients who returned to normal activity

	CN	APLD
Housework	72%	75%
Spare time activities	50%	46%

The main side effect that 30 CN and 7 APLD patients experienced was back-muscle spasms requiring analgesic drugs.

Conclusion: Trial results suggest that further controlled studies should be carried out before APLD can be considered a useful intervention.

- b. Krugluger conducted a study comparing APLD with chemonucleolysis (CN). The study initially selected 29 patients with symptomatic disc lesion confirmed by discography. (Krugluger 2000)

Epidural leakage of contrast material excluded 7 patients resulting in the randomization of the remaining 22 subjects to either CN or APLD.

Clinical and radiological data were recorded at 6 weeks, 12 months, and 2 years. The study placed emphasis on neurological symptoms and on the Oswestry score.

Automated Percutaneous Lumbar Discectomy (APLD)

Study Population:

Patient Demographics		
	CN	APLD
Number of patients	12 patients	10 patients
Average age	37 years	42 years
Lasegue's sign and sensory abnormalities	10 patients	8 patients
Weakness in a myotome related muscle	6 patients	5 patients
Abnormal reflexes	3 patients	1 patients
Duration of Back Pain	3 years	3 years
Duration of Leg pain	5 months	11 months
Herniation at L4-L5	4 patients	5 patients
Herniation at L5-S1	8 patients	5 patients

Results: At 6 weeks, both groups showed significant improvement in neurological deficits and Oswestry score. However, the differences between groups were not statistically significant. Follow-up at 12 months did not reveal further improvement in either group.

Two CN patients reported mild back pain and leg pain reappearing after 6 months. One patient developed nerve root symptoms after 3 months necessitating open discectomy.

Equipment failure caused one APDL patient to undergo an open operation. Another APDL patient required microdiscectomy 4 weeks after the initial procedure due to nerve root pain. Five APDL subjects experienced recurring back and leg pain that produced significant deterioration when compared both to earlier assessments and to the CN group.

The average time away from work for the CN group was 6 weeks.

Conclusion: Any further percutaneous techniques that are developed will have to give results that are superior to those produced either by chemonucleolysis or by microdiscectomy.

II. Randomized trials of APDL and microdiscectomy

- a. Chatterjee compared APDL to microdiscectomy in the treatment of contained lumbar disc herniation in a randomized study with blind assessment. (Chatterjee 1995)

Microdiscectomy was performed by standard technique with the removal of the herniated portion of the disc and all loose intradiscal material. APDL was performed with a 2 mm nonflexible automated suction nucleotome. Disc aspiration was continued until no more nuclear material could be obtained. The

Automated Percutaneous Lumbar Discectomy (APLD)

study offered microdiscectomy to patients who failed APLD and whose herniations were unchanged.

The clinician and a masked observer assessed all patients with the MacNab criteria at 3 weeks, 2 months, and 6 months.

The study intended to recruit 160 patients in order to achieve adequate power. However, inferior results in one group during the trial halted patient recruitment.

Study Population: The study included 71 patients who experienced radicular pain as their dominant symptom. They attempted conservative therapy for at least 6 weeks. MRI showed a contained disc herniation at a single level. Disc height was less than 30% of the sagittal canal size.

The study excluded patients with dominant symptoms of LBP, disc extrusion, sequestrations, subarticular or foraminal stenosis, or multiple levels of herniation.

Patient Demographics

	APLD	Microdiscectomy
L4-L5	12 patients	17 patients
L5-S1	19 patients	23 patients
Duration of LBP	18 months	33 months
Duration of radicular pain	13 weeks	20 weeks
Age	38.9 years	41.3 years

Results: Outcomes between groups was statistically significant.

Comparison of Outcome by Number and Percent of Patients

	Microdiscectomy	APLD alone	APLD → Micro	APLD alone and APLD → Micro
Excellent or Good	32/40 (80%)	9/31 (29%)	13/20 (65%)	22/31 (71%)

The mean length of hospital stay for the microdiscectomy group was 3.5 days and 5.3 days for microdiscectomy after APLD.

Three of the microdiscectomy patients failed to return to work or to their previous level of activity within 3 months.

Conclusion: APLD is ineffective as a method of treatment for small, contained lumbar disc herniation. If APLD is more effective in patients with a short history of radicular pain and a possibly less degenerated disc, then it is essential that further carefully controlled and randomized studies are performed to evaluate the efficacy of APLD as compared to more prolonged nonsurgical therapy.

Automated Percutaneous Lumbar Discectomy (APLD)

- b. Haines conducted a randomized study that had the primary objective of comparing APLD to conventional discectomy (CD) as a firstline treatment for herniated lumbar discs. (Haines 2002a) (Haines 2002b)

Randomization occurred through a permuted block design.

The study measured outcomes with physical signs related to the severity of LBP and sciatica, the Modified Roland Scale for disability assessment, and the SF-36 for general health status.

Four measures (average pain severity, use of pain medications, work activity and leisure activity) were combined in a matrix to produce an overall clinical outcome. The primary endpoint was the patient's outcome rating 12 months after surgery:

- Excellent – return to full time pre morbid work, no limitation in leisure activity, essentially no back or leg pain and no regular analgesics use
- Good – some restriction in work and leisure activity, occasional non-narcotic analgesic use, average pain score no higher than 3 on a 7 point scale

Success was defined as an excellent or good rating. Unsuccessful outcomes were defined as a fair or poor rating or a second surgical procedure on the same disc within 12 months of the initial operation.

Follow-up occurred at 1 week, 2 months, 6 months, and 12 months.

The study intended to recruit 330 patients with an expectation that 30 would be lost-to-follow-up. This would detect a difference of 15% at a significance level $P < .05$.

Study population: 34 patients were randomized to percutaneous discectomy (n=21) or CD (n=13). Of the 21 percutaneous subjects, 15 patients received APLD with the Nucleotome. 9 patients (5 APLD, 4 CD) were lost to follow-up.

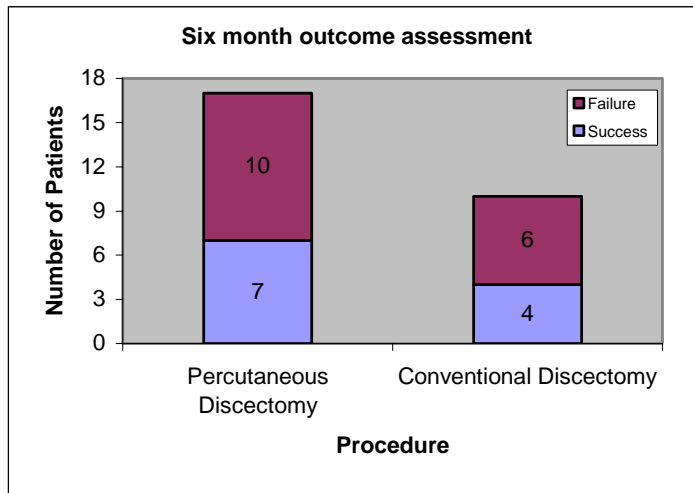
6-month follow-up was obtained on 27 patients, and 12-month follow-up was obtained for 19 patients. One patient randomized to CD actually received a percutaneous discectomy, but is analyzed as randomized.

The study included patients with unilateral leg pain or paresthesia with no history of lumbar spinal surgery. At least 2 of the following conditions were present: dermatomal sensory loss, myotomal weakness, reflex loss, positive straight leg raising, or femoral stretch test.

The study excluded patients due to moderate or advanced lumbar spondylosis, spondylolisthesis, lateral recess stenosis, herniated disc fragment occupying more than 30% of the AP diameter of the spinal canal, herniated disc fragment migrating more than 1 mm above or below the disc space, calcified disc herniation, lateral disc herniation, or posterior disc space height less than 3 mm.

Automated Percutaneous Lumbar Discectomy (APLD)

Results: Success rate of the two procedures was identical (APD 41%, CD 40%).



Outcome evaluation of SF-36 subscores and Modified Roland

	Preoperative	Postoperative
SF-36 subscores		
Physical functioning (mean)		
APD	36.0	74.7
CD	37.2	73.0
General Health		
APD	70.2	75.7
CD	66.5	70.0
Modified Roland		
APD	16.9	6.1
CD	17.3	6.5

Conclusion: The study did not have power to identify clinically important differences because of insufficient patient enrollment. As a result, the trial could not reach a definitive conclusion about the efficacy of standard and percutaneous discectomy.

Haines also states, “It is difficult to understand the remarkable persistence of percutaneous discectomy in the face of a virtually complete lack of scientific support for its effectiveness in treated lumbar disc herniation...If evidence should guide the treatment recommendations of physicians and surgeons to their patients, if evidence should guide the allocation of limited health care resources, if science has a role in evaluating surgical innovation, then the advocates of percutaneous discectomy should provide that evidence before asking their patients to undergo or pay for such procedures.”

Automated Percutaneous Lumbar Discectomy (APLD)

III. Case Series Studies

- a. Teng evaluated 1525 patients (mean age 48.2 years) with lumbar disc herniation or back pain that failed conservative therapy for 2 months. 950 patients had disc protrusion, and 357 patients had sequestration. 48 cases had calcification of disc or longitudinal ligament and 22 had previous surgical discectomy. (Teng 1997)

Patients were excluded due to previous chymopapain injection, progressive neurologic deficit or cauda equina syndrome, spinal stenosis, lateral recess stenosis, severe degenerative facet disease, or spondylolysis.

Results were judged as excellent, good, or poor. Excellent was defined as symptom free with no restriction in daily activities. Good was defined as greatly improved and return to work. Poor was defined as no improvement, worsening, or surgical discectomy or chemonucleolysis during the follow-up period.

Of the 1525 patients, 1474 patients were followed for at least 1 year. Mean follow-up after APLD was 18.3 months.

The average time between onset of symptoms to the procedure was 15.2 months.

Results: Excellent and good results were obtained in 56% and 26% of patients.

Number (%) of Patients with Excellent and Good Outcomes	
	Excellent and Good
L3-L4	82 (88%)
L3-L4, L4-L5	91 (88%)
L4-L5	372 (82%)
L5-S1	349 (83%)
L4-L5, L5-S1	235 (79%)
Extrusion/sequestration	258 (72%)
Bulging/protrusion	819 (86%)
Back and leg pain	1031 (80%)
Symptoms more than 2 years	516 (79%)
Age older than 60 years	1055 (84%)

Nine patients (0.06%) in this study developed discitis after APLD.

Conclusion: APLD with Teng's instrument has excellent results. Indications may include back pain alone. A straight needle can be used at L5-S1 in most patients, with proper positioning.

- b. Bernd observed 238 patients with disc protrusion or extrusion who failed 6 weeks of conservative therapy. The study also included patients without Lasegue's sign and without pathological preoperative neurological findings, such as sensory or motor deficits. (Bernd 1997)

Automated Percutaneous Lumbar Discectomy (APLD)

The study excluded patients due to isolated back pain, facet syndrome, degenerative disc disease, sacroiliac pathology, sequestered discs, or spinal stenosis.

182 patients (78.4%) of median age 41 years were suitable for evaluation at mean follow-up of 2.5 years. Patients were evaluated based on MacNab criteria, pain relief, patient satisfaction, activity, return to work and compensation claims.

Results: 52% of patients were satisfied with the outcome of the procedure. In 60%, pain decreased after APLD, and 15% reported being free of pain. Those without sensory deficit reported satisfaction (60%) more often compared to those with sensory deficit (43%).

The mean duration of inability to work was 8 weeks. Patients claiming compensation (n=7) were unable to work for a mean of 20 weeks.

Complications consisted of 2 cases of discitis. The risk for reoperation was 25%.

The only significant factor for a positive outcome with respect to improvement in condition and pain relief was age less than 41 years. A positive Lasegue's sign and an age of more than 41 years were risk factors for reoperation.

Conclusion: As the best results are achieved in younger, active patients with little neurological dysfunction, the authors state that APLD should play only a minor role in the treatment of lumbar pain related to disc herniation.

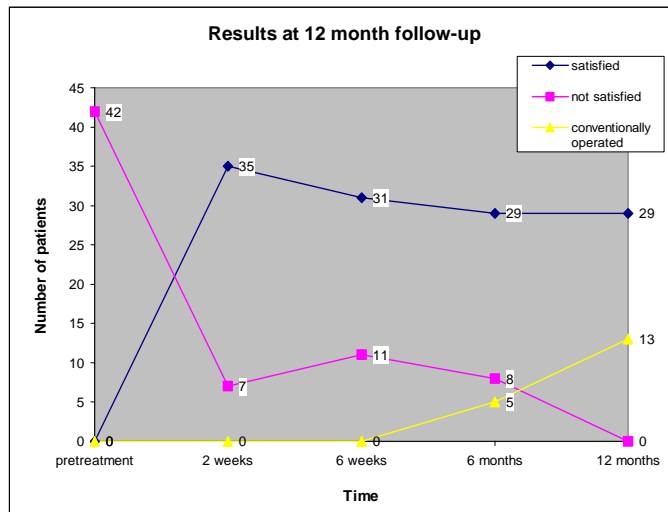
- c. Sortland observed for 1 year 45 patients (average age 35 years) from the Norwegian workers' compensation system. Patients experienced paresis, sensory alteration, or reflex alteration that did not respond to at least 6 weeks of conservative therapy. CT showed disc hernia protrusion less than 50% of the thecal sac and no sign of a free fragment. They did not have stenosis in the lateral recesses or in the spinal canal or spondylosis in the actual disc space. (Sortland 1996)

Cutting and suction were carried out until no more disc material could be obtained. Mean total procedure time was 85 minutes, and the weight of removed disc material ranged from 0.4 g to 7.7 g.

Follow-up occurred at 2 weeks, 6 weeks, 6 months, and 1 year.

Results: 42 patients treated with success had a history of back pain and sciatica with an average duration of 10 months. At one-year follow-up, 69% of the patients were satisfied. Of the 29 patients treated at the L4-L5 disc level, 9 later had conventional surgery. Of the 13 treated in L5-S1, 4 were later operated conventionally.

Automated Percutaneous Lumbar Discectomy (APLD)



Satisfied patients required an average of 11 weeks of sick leave. Unsatisfied patients were on sick leave until they underwent conventional operations.

No complications occurred.

Conclusion: Based on the strict criteria, 45 patients with small and medium sized disc hernias were chosen for percutaneous discectomy. Of the 42 patients who achieved technical success, 29 (69%) patients were successful at the 1-year follow-up.

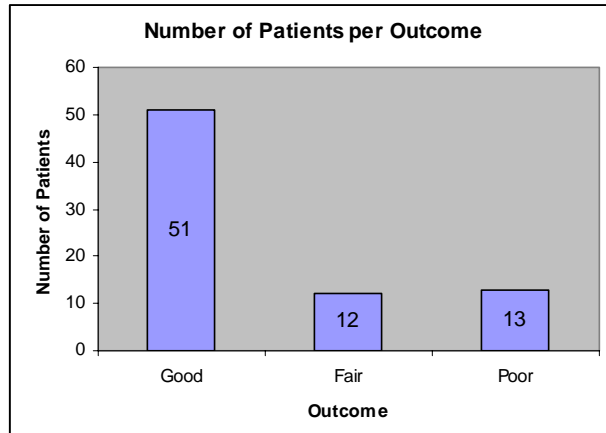
- d. Negri assessed 76 patients (mean age 45 years) who underwent percutaneous nucleotomy at L4-L5 (n=63), L3-L4 (n=12), L5-S1 (n=9), and L2-L3 (n=3). In 11 cases a two level approach was required for a total of 87 discs. All patients were followed for at least 12 months and up to 4 year. Patients attempted 6 weeks of rest or pharmacological treatment. (Negri 1996)

CT or MRI showed protrusion bulging in 36 cases, protrusion towards expulsion in 31 cases, expulsion in 7 cases, and sequester in 2 cases.

Clinical success was defined as a good rating with regression or considerable decrease in nerve root pain. Fair described some lumbar pain and moderate peripheral signs.

Results: Protrusion-bulging patients experienced no failures compared to patients with protrusion-expulsion who had a 34% failure rate. Expulsed patients had a 35% failure rate, and migrated patients a 100% failure rate.

Automated Percutaneous Lumbar Discectomy (APLD)

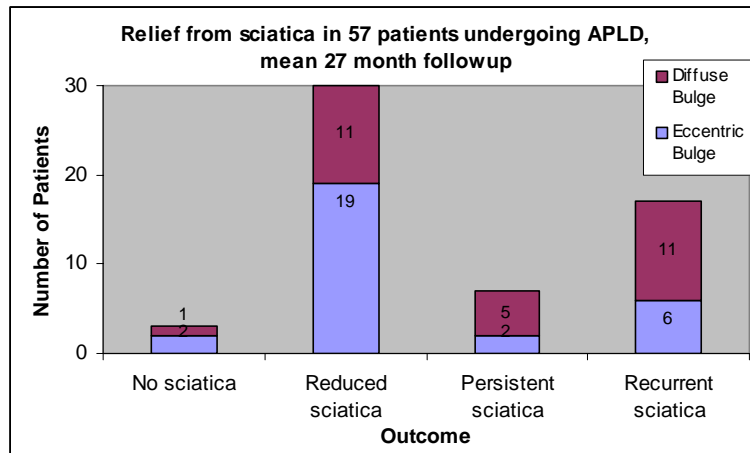


9 of 13 patients who did not obtain any improvement as a result of APLD underwent laminectomy. 2 other patients with less accentuated symptoms received peridural injections with a steroid base. The remaining 2 patients received vertebral traction and infiltrations of the interapophysary joints.

Conclusion: The best results were obtained in young, protrusion-bulging patients with acute symptoms and clinical signs corresponding to the nerve root involved.

- e. Shapiro examined 57 patients (mean age 45 years) with unilateral sciatica as their primary complaint. CT scan or MRI showed lumbar discs with either diffuse bulging or eccentric bulging. All patients had at least 6 weeks of conservative therapy prior to undergoing APLD at L3-L4 (n=4), L4-L5 (n=49), or L5-S1 (n=4). The overall amount of disc aspirate was 3.5 g. (Shapiro 1995)

Results: At 2 weeks, 50 (88%) patients had reduced sciatica, and all 47 with reduced sciatica who were employed preoperatively returned to work. At 2 months, 40 of 57 patients had reduced sciatica. Of the 10 recurrences of sciatica at 2 months, 7 subjects underwent lumbar microdiscectomy. At 2.5 years, sciatica recurred at a 34% rate.



Automated Percutaneous Lumbar Discectomy (APLD)

Patients with eccentrically bulging discs compared to diffusely bulging discs had a significantly better chance of reduced sciatica.

Conclusion: APLD is safe and in selected patients can reduce sciatica, but only completely eliminated sciatica in 5% of patients with a follow-up of 2.5 years.

- f. Grevitt examined 137 patients (mean age 33 years) with MRI confirmed disc protrusion. Patients had predominant leg symptoms, radicular pain distribution, restricted straight leg raise, and positive sign of nerve root tension. They also failed conservative treatment. (Grevitt 1995)

The study excluded patients with facet arthrosis, neurogenic claudication, and radiographs showing more than 50% loss of disc height. Patients with workers' compensation were also excluded.

The study includes in the final analysis 115 patients available at mean 55 months follow-up.

Results: 76% of patients were in full or part-time employment at last follow-up. If patients with a fair or poor outcome and those who had a further operation were considered as failures, the overall success rate was 45% (52/115).

There was a progressive deterioration in the health profile, and the mean transformed scores for the variables of mental health, energy/vitality and health perception were significantly lower than those of the general population.

- g. Fiume examined 200 patients (mean age 44 years) complaining of lumbo-sacral radicular pain due to herniated discs. The procedure was conducted at disc level L4-L5 (n=133), L5-S1 (n=45), and L3-L4 (n=22). 6 patients were treated at 2 levels. The study excluded patients due to spinal stenosis, lateral recess syndrome, disc calcification, severe neurological conditions, or recurrences at previously treated level. (Fiume 1994)

The study divided patients into two groups depending on severity of symptoms:

- Group A moderate root pain: 116 patients with radicular pain unresponsive to PT or analgesics for 2 or more months. They did not experience work impediment
- Group B severe root pain: 84 patients with pain for 2 or more months that impeded working ability

Excellent was defined as complete functional recovery and return to work. Good was defined as mild pain with return to work.

Operations lasted 21 minutes on average and removed a mean of 2.3 g of disc material.

Automated Percutaneous Lumbar Discectomy (APLD)

Results: 76% of cases experienced good to excellent results.

	Group A	Group B
Number of patients	116 patients	84 patients
Excellent or Good Results	98 patients (85%)	53 patients (64%)
Recurrences	2.5%	15%
Days to Pain Relief and Return to Work	13 days	24 days

The nucleotome was positioned correctly in only 34% of L5-S1 cases.

Conclusion: APLD has a high success rate and low morbidity rate in patients that are submitted for conservative care.

Adverse Events and Complications

Gill presented a case report of a 24 year-old male who underwent APLD at L5-S1 for relief of LBP. He developed new onset acute right lumbar radicular syndrome. MRI showed far lateral extraforaminal disc herniation at L5-S1 with compression of the right nerve. This corresponded to the nucleotomy site of the probe. (Gill 1994)

Dullerud's retrospective review of 243 patients treated at 271 disc levels showed 7 technical failures (2.6%). Of these, 6 failures were at the 5th disc level using a 2.5 mm nucleotome. Two patients developed clinical and radiological changes consistent with discitis. 9% of the patients reported mild spasm in the extensor muscles, and 25% of patients reported a mild to moderate sensation of instability. One patient developed functional paresis of the lower limbs one month after treatment. (Dullerud 1997)

Cost Study

Stevenson conducted a prospective cost evaluation including socioeconomic data comparing APLD to microdiscectomy.

Total and Average Cost for Each Patient Group: £s 1992 Pay and Prices

Treatment Group	Number of Patients	Total Cost (£)	Average Cost (£)
APLD only	11	8272	752
Microdiscectomy only	39	58,734	1506
APLD + Microdiscectomy	20	63,540	3177
Repeat Microdiscectomy	1	3931	3931

Average cost of treatment and follow-up surgery was £2317 per APLD patient compared to £1567 per microdiscectomy patient. The average cost per APLD successful outcome was £3264 compared to £1958 per microdiscectomy successful outcome.

Percutaneous Laser Discectomy (PLD)

Percutaneous Laser Discectomy

Percutaneous Laser Discectomy (PLD) is an alternative to the standard open discectomy treatment. PLD, first introduced by Choy in 1984, uses laser energy to reduce pressure by vaporizing a small volume of the nucleus pulposus. Laser energy transmitted in the form of light is transformed into heat. The thermal energy raises the tissue temperature to boiling and vaporization occurs. It is hypothesized that the change in pressure between the nucleus pulposus and the peridiscal tissue causes retraction of the herniation away from the nerve root. (Caspar 1995) (Bosacco 1996) (Choy 1998)

Lasers have different characteristics, energy requirements, and rates of application. Medical lasers consist of four basic components: the laser medium, an energy source, a feedback mechanism like a series of mirrors, and an output coupler. Lasers and wavelengths used in the intervertebral disc are (Caspar 1995):

- KTP (potassium-titanyl-phosphate) at 532 nm
- Nd:YAG at 1.064 and 1.44 μm
- CO₂ at 10.6 μm
- holmiumYAG at 2.1 μm

Published Studies

I. Case Series Study with Historical Comparison Group

- a. Bosacco evaluated the KTP 532 laser for its use in contained, small to moderately sized disc herniation. The laser system was set at 10 W, and laser pulses were delivered for 0.2 seconds. A total of 1250 J was delivered to the disc space. (Bosacco 1996)

Outcomes were assessed with the following criteria:

	Pain	Return to function	Postoperative stay	Return to work interval
0	No relief	Disabled	3 days	6 weeks
1	Partial relief, medication	Function level unchanged	Less than 3 days	Less than 6 weeks
2	Partial relief, no medication	Increased, but not premorbid function		
3	Pain free	Return to premorbid function		

Study Population: Of the 63 patients who underwent PLD, 61 patients (mean age 48 years) were available at average 31.75-month follow-up.

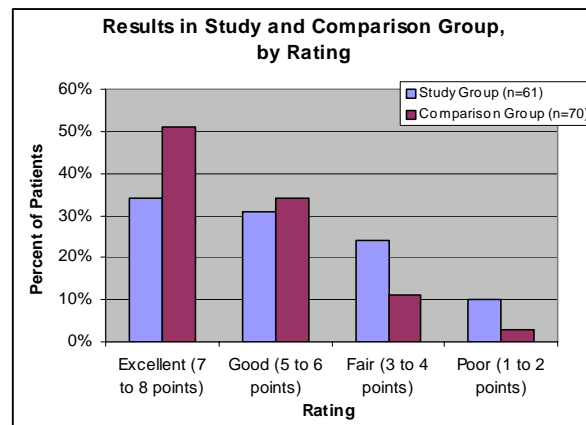
The study also included a retrospective comparison group of 70 patients who were treated with open discectomy (mean age 45 years).

Percutaneous Laser Discectomy (PLD)

Inclusion criteria were single nerve root signs and symptoms, positive straight leg raising test, and disease at only L4-L5. MRI findings showed a focal, asymmetric annular protrusion into the spinal canal that did not occupy more than 25% of the canal.

Subjects were excluded due to previous surgery, spinal stenosis, disease at more than one level, or extruded or sequestered disc fragments.

Results: 17 patients had complete pain relief, and 40 patients had partial relief.



One patient developed acute urinary retention with reflex ileus.

A previous report showed that the open surgical treatment of lumbar disc disease in workers' compensation patients resulted in an 80% rate of permanent disability. If compensation patients were excluded from this study, the success rate would have been 76%.

Conclusion: PLDD is a safe and successful alternative for the treatment of patients with a small to moderately sized herniated nucleus pulposus. Satisfactory relief of radicular pain is to be expected.

II. Prospective Case Series Study without Comparison Group

- a. Gronemeyer investigated whether PLD with the Nd:YAG laser reduced pain, sensorimotor impairment, and medication consumption. (Gronemeyer 2003)

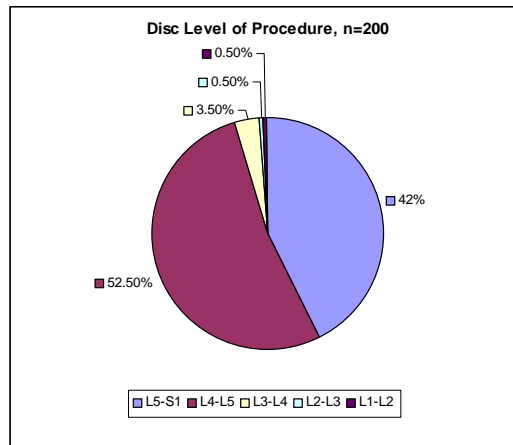
Using CT/fluoroscopy guidance, a cannula helped with placement of a 400-nm laser fiber. The laser procedure involved 1-second pulses of 10 W until an overall energy of 1100 to 1200 J was reached.

Percutaneous Laser Discectomy (PLD)

Study Outcomes

Pain Scale	Sensorimotor Impairment	Pain Medication	Sick Days
None Clear reduction Mild reduction No reduction		Reduced Unchanged Increased	Decreased Remained the same Increased

Study Population: The study included 200 patients (mean age 46 years). 165 patients had neurological deficits in addition to pain, and 171 patients reported use of pain medication.

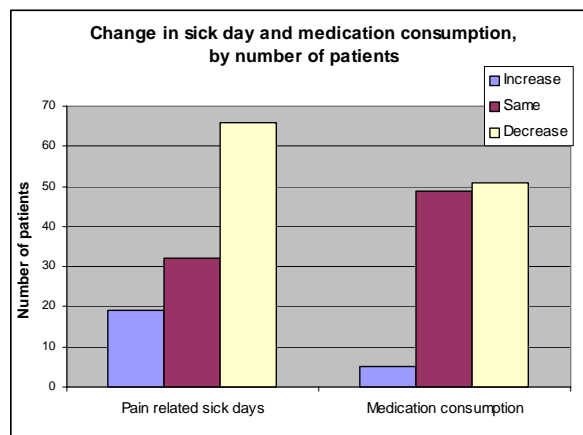
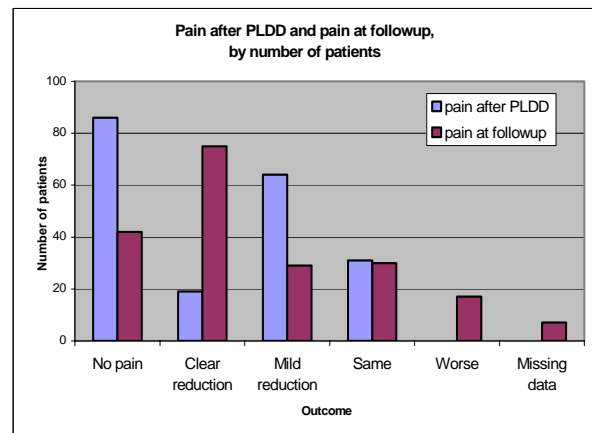
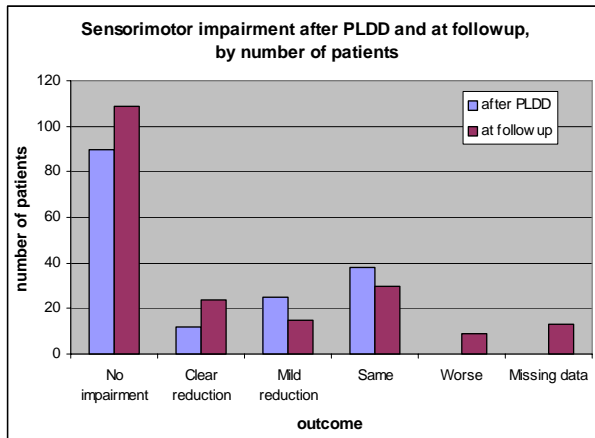


Patients experienced radicular pain with or without neurological signs. CT or MRI confirmed the contained disk herniation. All patients failed at least 6 weeks of conservative therapy.

The study excluded patients with nondiscogenic root compression, narrow spinal canal or intervertebral space, dislocated sequester, tumor, spondylolisthesis, pseudospondylolisthesis, a mass prolapse with decompression of the dural sac and the cauda equina, or facet syndrome.

Results: Immediately after PLD, 86 patients were pain free. 83 patients experienced a reduction in pain that lasted an average of 3.1 years. At 4-year follow-up, 148 patients reported that they were satisfied with outcomes.

Percutaneous Laser Discectomy (PLD)



One patient developed discitis.

Conclusion: The researchers suggest that the Nd:YAG laser is a safe and effective method to treat symptomatic contained intervertebral disk herniations

- b. Tonami studied whether immediate postoperative MRI could show early tissue changes after PLD with the Ho:YAG laser system. The study also correlated MRI findings with clinical outcomes. (Tonami 1997)

The laser power was set at 1 to 1.6 J per pulse repeating at 10 to 12 J per second. The procedure was terminated when total energy reached 20 kJ.

Patients underwent MRI 24 hours after PLD. Surface measurement related the size of the herniated mass to that of the spinal canal. Signal intensity of the herniated disc was also related to that of the adjacent vertebral body.

The study assessed clinical outcomes with the Japanese Orthopaedic Association (JOA) scale (29 points). Success was defined as a recovery rate of over 25%.

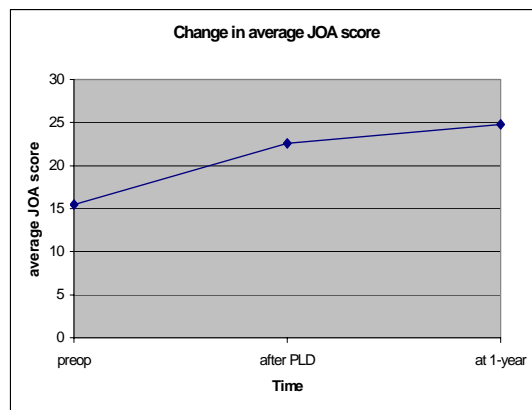
Percutaneous Laser Discectomy (PLD)

Study Population: PLD was performed on 29 discs in 26 patients (mean age 35 years).

Inclusion criteria were radicular leg pain with or without LBP; motor, sensory, or reflex deficits; contained disc herniation; and 3 months of conservative treatment.

Subjects were excluded due to non-contained or sequestered herniations or previous disc surgery.

Results: The average recovery rate after treatment was 53.1% and 64.6% at 1 year. Three patients with recovery rates below 25% underwent additional surgeries.



Although most patients improved clinically after PLD, no patient showed an obvious change in disc herniation size. Researchers did not detect correlations between herniation size and recovery rate or between signal changes within the disc and the recovery rate.

MRI showed soft tissue changes along the laser tract caused by PLD in 5 patients.

Conclusion: Although postoperative MRI showed early tissue changes from laser exposure, the study did not prove whether MRI could predict clinical outcome after PLD.

- c. Nerubay conducted a study using a CO₂ laser on 50 patients. Laser energy was delivered in four 30-second periods interrupted by a 30-second pause. The system delivered 8 watts during a 2-minute period. (Nerubay 1997)

The study assessed outcome with the MacNab criteria:

- Excellent - no pain and no activity restriction.
- Good - occasional back or leg pain, pain that interferes with ability to do normal work or enjoy leisure time.
- Fair - improved functional capacity, but handicapped by intermittent pain that curtails or modifies work or leisure activities.
- Poor - no improvement or insufficient improvement to increase activities.

Percutaneous Laser Discectomy (PLD)

Follow-up occurred at 1 week, 1 month, 3 months, and 6 months, and every 6 months thereafter. The average follow-up was 2 years and 8 months.

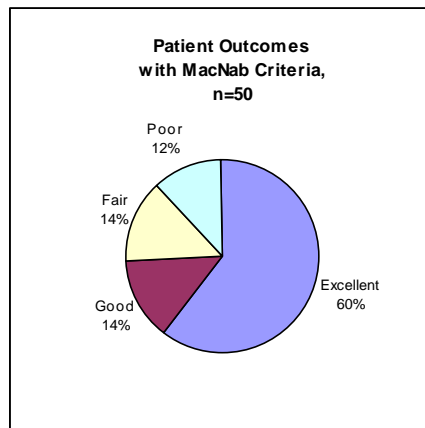
An independent neuroradiologist examined CT and MRI findings.

Study Population: The 50 patients had a mean age of 34 years and mean duration of pain of 33 months. 22 (44%) subjects reported sensory disturbance, and 16 (32%) subjects reported motor disturbance.

The study included patients with LBP and radicular pain that did not respond to conservative treatment for 3 months. Radiographs, CT, or MRI showed a L4-L5 disc lesion.

The study excluded patients due to spinal stenosis, spondylolisthesis, degenerative disc disease, previous back surgery, or huge protruded or extruded disc.

Results:



Change in the size of the herniated nucleus pulposus

	Number (%) of patients
No change	29 (58%)
Slight decrease	14 (28%)
Marked decrease	7 (14%)

In 6 patients, changes in the end plates suggested thermal damage. No correlation was found between clinical outcome and CT and MRI changes.

Four patients had signs of root irritation probably caused by thermal damage to the root.

Conclusion: The use of lasers is still an experimental procedure. More research is needed, and endoscopic control will be necessary to obtain better results.

Percutaneous Laser Discectomy (PLD)

- d. Liebler conducted a study with different lasers delivering 1200 to 1500 J of energy. If heat expanded the disc and caused discomfort, the surgeon paused until the heat dissipated. (Liebler 1995)

The study used the MacNab criteria to assess outcomes and averaged the scores by disc level. Follow-up occurred at 24 hours, 6 weeks, 3 months, 6 months, and 1 year. At Week 3 or 4, patients began a back strengthening program.

Study Population:

Patient Demographics

	2-Year Follow-up	1-Year Follow-up
Number of patients	23	36
Type of laser	KTP laser	Nd:YAG
Duration of pain	43.8 months	13.8 months
Age	43 years	47.3 years
Weight	153.2 pounds	155.8 pounds

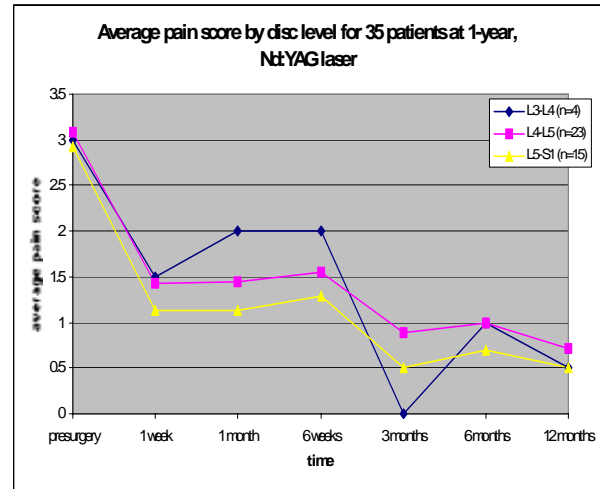
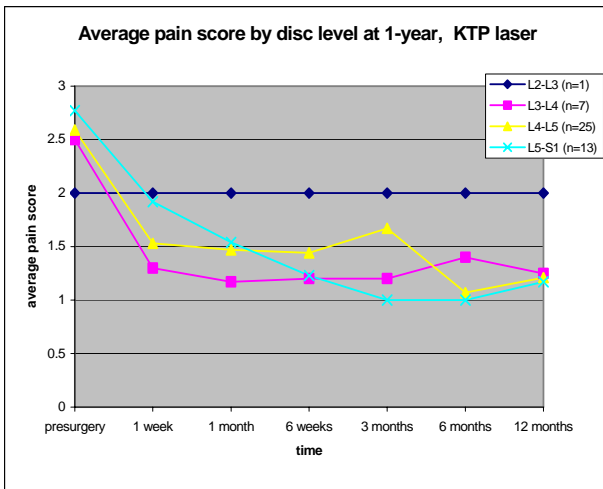
The study included patients with a history of lumbar, leg, or lumbosacral leg pain with positive neurologic findings. They had not had previous surgery or chemonucleolysis. CT scan, myelogram or MRI showed a bulging contained disc. Patients attempted at least 6 weeks of conservative therapy.

Patients were excluded due to stenosis or facet syndrome, spondylolisthesis, advanced disc degeneration, workers' compensation or disability litigation, or cauda equina syndrome.

Results:

Results at one year by laser type

	KTP laser	Nd:YAG laser
Good	75%	70%
Fair	15%	16%
Poor	10%	14%



Percutaneous Laser Discectomy (PLD)

- e. Simons used a 1064 nm Nd-YAG laser to apply 10 W pulses of 1-second duration followed by a 5-second pause. The average delivered energy equaled 1171 J/disc. (Simons 1994)

The study used the following criteria to assess the effect of the laser.

- Very good - no neurological deficit, free of pain, return to work
- Good - minor complaints, no medication needed to return to work
- Satisfactory - more complaints under strain, return to part-time work, medication needed
- Failure - major complaints or microdiscectomy needed, no return to work

On average, first follow-up occurred at 184 days.

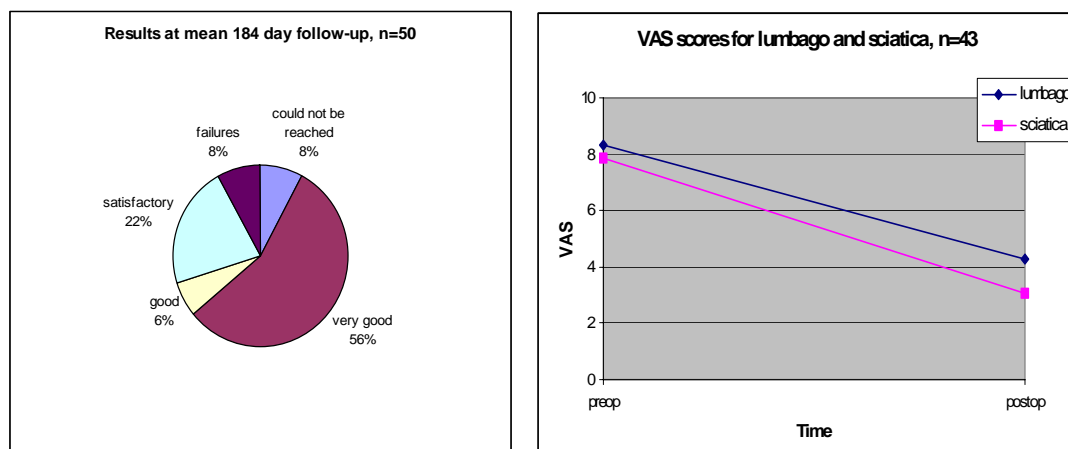
Study Population: PLD was conducted in 50 patients on 55 lumbar discs (20 L5-S1, 31 L4-L5, 4 L3-L4)

The study included patients with nerve root compression who did not respond to more than 3 months of conservative therapy. MRI verified the lumbar disc protrusion.

Patients were excluded due to pareses greater than grade 4 out of 5 and severe bony compression.

Results: 43 patients experienced satisfactory, good, or very good results. Pareses in these 43 patients were reduced to 20% of preoperative findings and the Lasegue sign was reduced by half.

After surgery, 26 of 35 patients returned to the same job or worked in modified settings. 3 were studying for another job, and 6 could not return to work because of complaints.



Conclusion: Laser denaturation reduces lumbar nerve root compression. The results showed a low complication rate.

Percutaneous Laser Discectomy (PLD)

Costs

One surgeon reported in 1996 that the average hospital cost for PLDD was \$3720. This was 35% of the average hospital cost for open discectomy, \$10,600. Total operating time assumes a 3-hour procedure for open and 1 hour for PLDD. (Bosacco 1996)

Other Payer System Reviews

In 2000, a review for Australia classified PLD as level 2 stating “The safety and/or efficacy of the procedure cannot be determined at the present time due to an incomplete and/or poor quality evidence-base. It is recommended that further research be conducted to establish safety and/or efficacy.” The review recommended randomized controlled trials to test PLD against placebo, chemonucleolysis, or open discectomy. (Boult 2000)

Nucleoplasty

Nucleoplasty

Nucleoplasty is a percutaneous procedure intended to treat discogenic back pain through decompression. Nucleoplasty uses the Perc-D Spine Wand, a 1 mm diameter bipolar probe that decompresses the disc nucleus with energy and heat. This Coblation technology generates a low temperature plasma field for controlled ablation.

The wand tip generates a plasma field, which is a millimicron thick field of energized particles that can break organic molecular bonds in disc material. This creates a channel through the annulus. On probe withdrawal, the coagulation mode is used. The thermal effect results in denaturization and shrinkage of the collagen thereby widening and thermally treating the channel. Thus, nucleoplasty combines coagulation and tissue ablation (patented Coblation technology) to form channels in the nucleus and decompress the herniated disc.

The technology is designed so that most of the energy applied is used to ablate, with minimal amounts dissipating as heat into tissue. The by-products of this non-heat driven process are elementary molecules and low-molecular weight inert gases, which are removed from the disc via the needle. (Sharps 2002) (Welch 2002) (ArthroCare 2003) (Chen 2003)

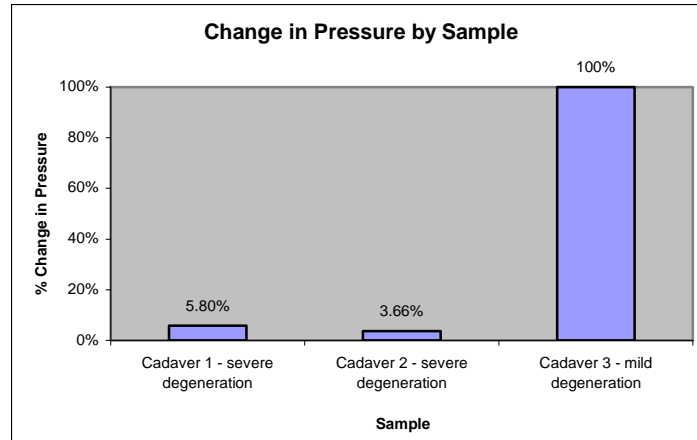
Food and Drug Administration (FDA) Approval

The FDA granted 510(k) approval to ArthroCare in 2001 for the marketing of the Perc-D Spine Wand. The wand is approved for “ablation, coagulation, and decompression of disc material to treat symptomatic patients with contained herniated discs.” It is classified under Electrosurgical Cutting and Coagulation Device and Accessories. (FDA 2001)

Effect of Disc Degeneration on Outcomes

Chen analyzed the influence of disc degeneration on intradiscal pressure change after nucleoplasty in 3 cadaver spines. Intradiscal pressure was markedly reduced in the younger, healthy disc. In the elderly cadavers, the small intradiscal pressure reduction (less than 2 psi) had little clinical impact on overall disc pressure. (Chen 2003)

Nucleoplasty



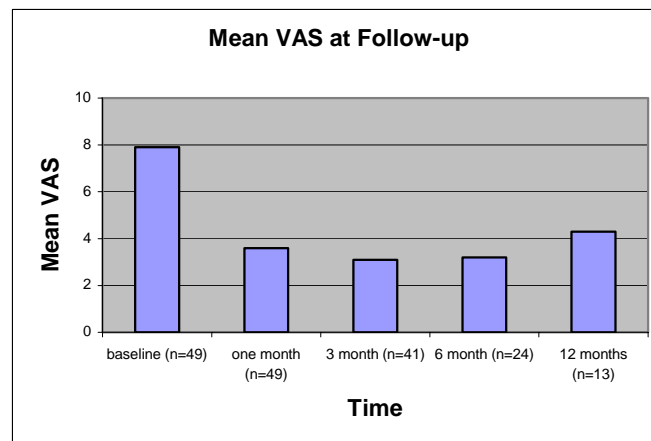
This study demonstrated that nucleoplasty's pressure-reducing effects are dependent on the degree of spine degeneration. Although disc material has been removed, the dehydrated fibrotic nature of the degenerated discs prevents decompression that reduces intradiscal pressure. The treatment is ineffective for severely degenerated discs.

Case Series

a. Sharps evaluated 49 patients (mean age 38 years) who had back pain with or without radicular pain. The study excluded patients due to sequestered herniation, contained herniation larger than 1/3 the sagittal diameter of the spinal canal, or stenosis. (Sharps 2002)

The study evaluated a pain VAS at 1 month, 3 months, 6 months, and 1 year. Success was defined as a 2 point reduction on the VAS, patient satisfaction, no use of narcotics, and return to work.

Results:



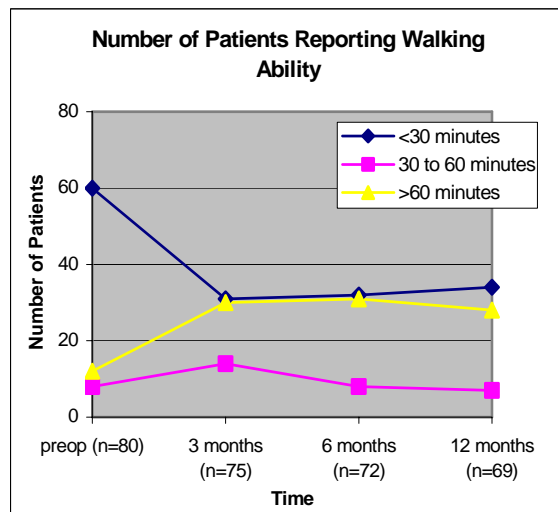
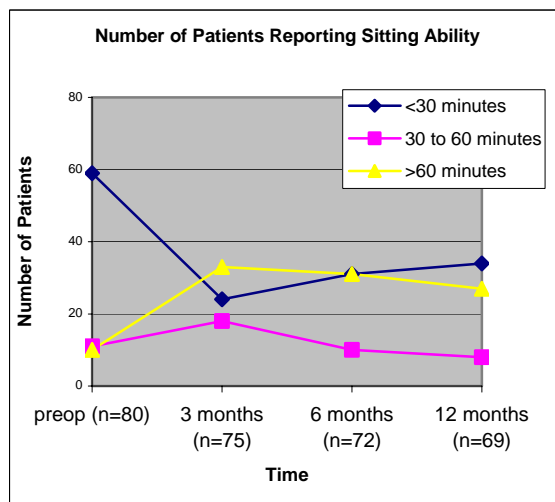
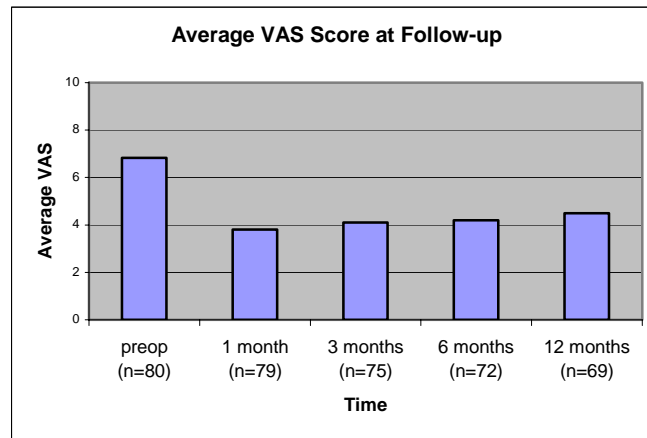
Conclusion: Prospective randomized studies with long-term outcomes would delineate for whom the procedure is helpful.

Nucleoplasty

b. Singh evaluated 80 patients (average age 44.8 years) who had LBP and/or leg pain for 3 or more months that failed conservative therapy. Patients were excluded due to secondary gain issues, heavy opioid usage, sequestration, large contained herniation occupying more than one-third of the spinal canal, or stenosis due to osteophytosis.

The study assessed patients at 1, 3, 6, and 12 months with a pain VAS and functional improvement. 69 patients were analyzed at 12 months.

Results: At 12 month follow-up, 52 of 69 subjects (75%) reported a decrease in pain score.



Ten patients previously unemployed due to back pain returned to work.

No complications were reported.

Conclusion: The authors concluded that the study demonstrated a statistically significant improvement in pain and function at 12 months.

Coding and Insurers

The applicable code for these series of procedures is 62287, “Aspiration or decompression procedure, percutaneous, of nucleus pulposus of intervertebral disk, any method, single or multiple levels, lumbar (e.g., manual or automated percutaneous discectomy, percutaneous laser discectomy).”

Percutaneous Lumbar Discectomy

BlueCross BlueShield of Massachusetts (2000) and Humana (2000) do not cover Percutaneous Lumbar Discectomy.

BlueCross BlueShield of North Carolina (2003) covers Percutaneous Lumbar Discectomy, a procedure where the herniated disc is scraped, suctioned or lasered until pressure on the irritated nerve is relieved. Percutaneous Lumbar Discectomy is eligible for coverage when:

- Diagnostic imaging shows an uncomplicated herniated lumbar disc with no evidence of a detached fragment or disc separated from the vertebral column.
- Acute unilateral leg pain is localized to a single area, indicating a single spinal nerve affected OR acute and intractable back pain is consistent with disc herniation without fragmentation or separation of the disc from the vertebrae.
- Neurologic signs or symptoms are consistent with disc herniation without fragmentation or separation of the disc from the vertebrae, i.e., sensory abnormalities, altered reflexes, a positive straight-leg raising test, or weakness.
- MRI, CT or myelography show herniation of a single lumbar disc (L1 -L2 through L5 - S1) that is consistent with the signs and symptoms of disc herniation without fragmentation or separation of the disc from the vertebrae.
- Conservative therapy has failed to relieve pain and other signs and symptoms, thereby making the patient a candidate for surgery

Percutaneous Lumbar Discectomy is not medically necessary for BCBS NC patients with physical or diagnostic imaging evidence of disease other than an uncomplicated herniation of a single lumbar disc. Complications include evidence of a fragment or disc separated from the vertebrae and the clinical indications below:

- Progressive neurologic dysfunction
- Impairment of the bowel or bladder function
- Evidence of vertebral disease such as spinal stenosis (narrowing or stricture of the spinal canal) or spondylolisthesis (disc is slipped forward in relation to adjacent vertebra).

Percutaneous Laser Discectomy

The Regence Group (2003) does not cover percutaneous laser discectomy because it is considered investigational.

Coding and Insurers

In 2003, the National Institute for Clinical Excellence of the United Kingdom chose to provide laser discectomy. Physicians are instructed to discuss the safety and efficacy uncertainties with their patients. Patients must provide consent, and physicians must monitor outcomes. (NICE 2003)

Nucleoplasty

The following insurers do not cover nucleoplasty because it is considered investigational.

- Aetna (2003)
- BlueCross BlueShield of Alabama (2003)
- BlueCross of California (2003)
- Medicare of Kansas, Nebraska, and Northwest Missouri (2003)
- The Regence Group (2003)

Conclusion

Percutaneous discectomy procedures are minimally invasive surgeries that act as alternatives to conventional discectomy. Many studies have been conducted on the array of percutaneous discectomy procedures. The quality of the studies ranged from randomized trials to case series studies. Most of the studies were small, case series studies without comparison groups. As a result, these studies did not conclusively show treatment efficacy.

Two randomized trials of manual percutaneous discectomy have indicated that the percutaneous groups experienced shorter disability duration. The first randomized trial comparing arthroscopic to open discectomy showed comparable clinical results between treatment groups at mean 31 months. The second study comparing percutaneous to microdiscectomy also showed comparable clinical results at 2-year follow-up. While the results were promising, these two trials do not show that manual percutaneous discectomy is more efficacious than the gold standard conventional discectomy.

APLD has also been compared to alternative treatments. In one trial against chemonucleolysis, chemonucleolysis patients experienced better outcomes at both 6 months and 1 year. A second study showed comparable results between chemonucleolysis and APLD patients. When APLD was compared to microdiscectomy, researchers halted study recruitment due to poor outcomes experienced by the APLD group. A small study examining APLD against conventional discectomy showed comparable results between the two groups, but the study did not have adequate power to detect significant findings. Although the studies were all small trials, they generally found that chemonucleolysis and microdiscectomy resulted in better patient outcomes.

No randomized trials have been conducted to study the efficacy of either percutaneous laser discectomy or nucleoplasty. One study of laser discectomy included a historical comparison group of patients who underwent open discectomy. The authors note that the comparison group generally showed stronger results, but the laser group would have had a higher success rate if compensation patients had been excluded from the study. Because only case series studies have been conducted to examine the efficacy of these two procedures, they are considered investigational.

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