Intervertebral Differential Dynamics Therapy

By C. Norman Shealy, MD, PhD

The author reviews the evolution of back pain technology and presents results of a study utilizing differential dynamics rehabilitation.

The annals of medicine offer countless examples of widely used diagnostic and treatment protocols that represented the standard of care for the time. Through clinical observation and data analysis, physicians are able to identify necessary refinements for improving outcomes. In essence, an evolution takes place yielding better refined, more effective standards of care.

Consider for example, the standard of care established over six decades ago for diagnosing ruptured intervertebral discs, namely Pantopaque® myelography. Although it provided excellent radiological contrast, twenty-five percent of patients developed adhesive arachnoiditis after a single myelogram — leading to progressive disability far worse than the ruptured disc. Fortunately, MRI replaced the more risky Pantopaque myelogram, giving rise to a more refined standard of care. The MRI, a more specific diagnostic approach, proved highly effective and much less traumatic to the patient.

Now consider one of the standards of care for low back pain. Although some form of spinal traction/distraction was used for centuries, the results were erratic and inconsistent, so that most spinal specialists began to abandon this approach in the 1960's.[1] Then Burton and Nida introduced the concept of gravity lumbar reduction therapy.[2] They literally strapped patients upright in a harness for eight hours a day, for one to four weeks, with results best in patients with ruptured discs. However, the complication of hypotension and eight hours of immobilization doomed this radical approach.

Back to the Drawing Board

In 1996, the author was asked by an emerging company to evaluate a pneumatic traction/distraction device that reputedly "decompressed" the lumbar spine. The author was shocked to see patients required to hold themselves in the prone position manually with their arms and hands overhead for 30 minutes of considerable distraction. Five, of six patients interviewed, reported significant shoulder discomfort. The author's attempt on this device resulted in a subluxation of the right shoulder, resulting in several weeks of shoulder pain. Even more troubling was the observation that the prone position actually increased lumbar lordosis — clearly undesirable for optimal spinal dynamics. It occurred to this author that it was definitely no great improvement over the old Hippocratic technique of strapping a patient upright on a door that was dropped out a window!

Optimal Mechanisms

The author evaluated the mechanisms considered optimal for lumbar decompression, reduction and stabilization. Working with several models, x-ray confirmation, and manual palpation, the following conclusions were reached for optimal mechanical distraction of the lumbar spine:

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 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,
7. a graduated limbering, strengthening and stabilization exercise program,
8. angle of distraction ranging from 10 to 30 degrees.

In the author's review and experience, as of a decade ago, no single device incorporated all these major factors that are important in achieving clinical results. Yet using these guidelines led to vertebral distraction of 7 to 15 millimeters and good to

excellent pain relief. Of 14 patients having MRI-confirmed ruptured discs with surgery recommended, only one subsequently required surgery. Of eight patients with degenerative disc disease or facet arthrosis, six achieved good to excellent pain relief.[3]

Device Evolution

Continuing evolution of the technology discussed above has led to further improvements now being incorporated in new generation devices utilizing computer-directed physical therapy of the lumbar spine, along with refinements of treatment protocols employing differential dynamic rehabilitation.

Treatment objectives include freeing a locked facet joint, correcting spinal misalignment which has rendered it dysfunctional, relieving pressure on a nerve root, or bulging disc, stimulating inhibition of annular fluids, restoration and rehabilitation of normal spinal function and the underlying musculature that is typically compromised.

Comfort during the treatment has improved as well as the ability to focus therapeutic force on specific vertebral levels with optimum mobilization, manipulation, and clinical relief. The ability to utilize multiple primary waveforms, as well as a secondary oscillatory waveform designed more specifically to apply a neuromuscular component, further illustrate the progression evolution of this rehabilitative therapy. Active tracking of applied forces, the ability to individualize treatment according to patient needs and the ability to quantify patient response to the treatment regimen pre- and post-therapy sessions further improves therapeutic results.

The device used in the following study was the Accu-SPINA™, manufactured by North American Medical, and utilizing the 'Intervertebral Differential Dynamic (IDD®) Therapy' protocol.

Study Results

The author was able, as an independent consultant, to review results currently being reported from ten clinics comprising a cohort of over 500 patients. Improvement rates of 65 to 88% confirm the author's earlier findings regarding differential dynamic rehabilitation. Most importantly, the latest study demonstrates not only an average 65% decrease in pain at completion of IDD therapy, but average pain reduction of 76% one year after treatment (see Figure 1, courtesy of North American Medical).

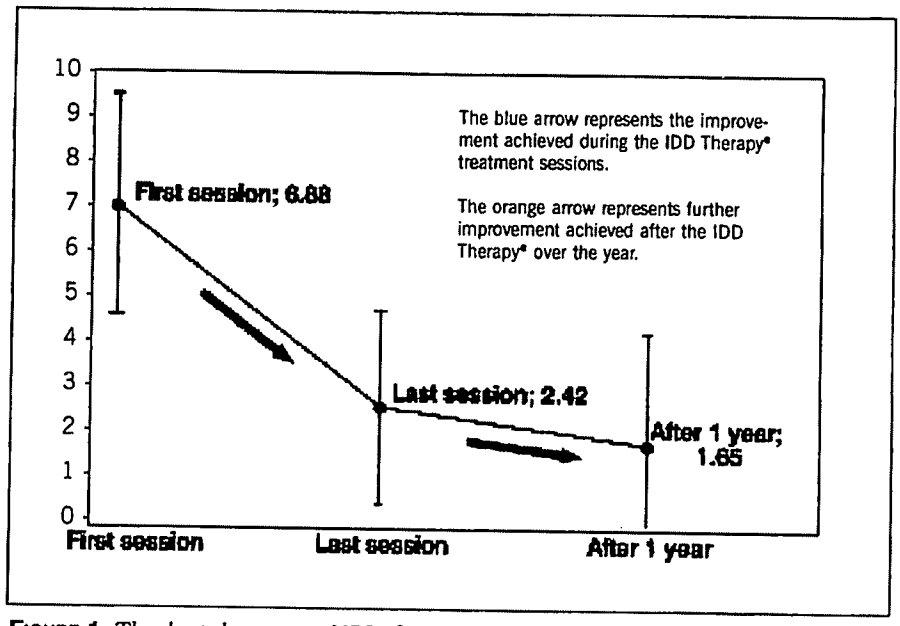

FIGURE 1. *The chart shows mean NPS of 6.88 at the beginning of IDD Therapy® treatment after the completion of treatment the mean NPS is reduced to 2.42 (last session). After a duration of one year the patients continue to improve and the mean NPS is 1.65.*

Current exploration of vibration, distraction, oscillation and other adjunctive mobilization adjustments offer even greater potential for the future of inter-vertebral differential dynamics rehabilitation.

Summary

During the past decade, computerized technology has markedly increased successful outcomes of non-surgical physical therapeutic mobilization for spinal pain, including ruptured discs, as well as locked and degenerative facet pain syndromes. Specific individual spinal segment dynamic mobility leads to satisfactory pain relief and improved quality of life in up to 88% of patients — many of whom have failed other "conventional" approaches. Based on author's review of recent study results, inter-vertebral differential dynamic rehabilitation appears to be the current optimal recommendation for most lumbar pain syndromes. ■

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Acute disc injury and discogenic pain is one of the primary processes leading to low back pain and lumbar radiculopathy, although the pathophysiologic mechanisms are still not well understood. It is believed that increases in disc pressures resulting from heavy lifting, vibrational and postural forces etc. are important factors in the pathogenesis of low back pain. The effects of disc hydraulics in herniations or protrusions may cause a mechanical deformation of the nerve roots and a compression-induced impairment of the vasculature. In addition, it has been found that the biochemical properties of the nucleus pulposus may induce a toxic or inflammatory reaction in the nerve root.

There have been many studies indicating that the disc and its associated pathology are identified as a primary cause of low back pain and lumbar radiculopathy. Hirsch stimulated various lumbar tissues in awake patients with the use of carefully placed needles. (5) Stimulation of the posterior portion of the annulus produced low back pain in many individuals. Furthermore, he was able to eliminate the pain by the injection of a minute volume of local anaesthetic into the annulus. Smythe and Wright placed nylon threads into various lumbar tissues while performing lumbar spinal operations. (6) During the postoperative period, they pulled on the threads and asked the patients to describe the location of any pain produced. The annulus fibrosus was the most common site of low back pain, and the compressed nerve root was responsible for sciatic pain. Tension placed on a normal nerve root resulted in no pain.

Falconer and associates published their observations made during exploration of the lumbar spine under local anaesthesia. (7) Murphy reported similar results in his small series of surgical cases. (8) Both authors concluded that the annulus and nerve root were the pain generating tissues. Wiberg in 1950, operating on 200 patients using local anaesthesia of the skin and muscles only, reported that pain emanated from the disc. (9) Kublisch operated on 193 patients using local anaesthesia and drew certain conclusions about the likely origin of back and leg pain. (10) Sciatica could only be produced by stimulation of a swollen, stretched, or compressed nerve root. Back pain was produced in the majority of cases by stimulating the outer layer of annulus fibrosus and the posterior longitudinal ligament.

If the disc is a major source of low back pain then applying specific target therapy for the treatment of disc pathology should improve patient outcomes. VAX-D is a primary, non-surgical treatment for the management of patients with disabling low-back pain and neurological symptoms associated with herniated and degenerative disc disease. Research has shown that the VAX-D table is a decompression device that is capable of reducing intradiscal pressures to negative levels. (11)

Successful reduction of intradiscal pressures with VAX-D represents a technological advance that should provide a means of addressing compressive disc pathology. Creating negative intradiscal pressure is likely to affect both the biomechanical and biochemical causes of discogenic pain. Patients suffering from discogenic pain and/or associated sciatic pain are seeking conservative treatment without the risks associated with injections and surgical procedures.

VAX-D incorporates advanced technology that permits the application of distractive tensions without eliciting reflex muscle guarding. Conventional traction devices have not demonstrated this ability or the ability to reduce intradiscal pressures to negative levels. Studies published in the medical literature report that intradiscal pressure either remains unchanged or

increases during traction. (12) It has also been demonstrated that paraspinal muscles are not able to fully relax during conventional traction.

The beneficial effects of VAX-D decompression in the relief of peripheral nerve dysfunction has been previously reported in the literature, (13) and a multi-center outcome study reported that VAX-D treatment was successful in 71% of the 778 cases studied. (14).

This study was designed to evaluate the effect of VAX-D on chronic low back pain.

Material and Methods

In association with Quintiles, the world's largest health care consultancy organisation for data analysis in clinical trials, a protocol was developed and then approved by the Human Research Ethics Committee at the University of Wollongong, New South Wales, Australia.

It was predetermined that the treatment would be considered a success if the patient attained a fifty percent (50%) decrease in pain, numerically on the Visual Analogue Scale (VAS). Absolute changes in pain score determined by VAS over time were analysed with repeated measures analysis of variance and *t*-test. In addition, improvements in disability were recorded on a patient nominated disability rating. Any level of improvement in disability was acceptable. The instruments for determination of these outcomes were supplied by the National Musculoskeletal Initiative of Australia. The study itself was to be conducted in the medical clinics of the VAX-D Spinal Institute and so to prevent bias in the data collection Quintiles were engaged to collect and analyse the data. TENS was selected as an appropriate placebo treatment as a means of establishing a plausible but (probably) ineffective control for an unblinded treatment.

Through advertisement in local papers forty-four patients with chronic low back pain greater than 3 months in duration, with associated leg pain, and a confirmed disc protrusion or herniation on CT Scan or MRI were selected and randomised into the two treatment methods, either VAX-D or TENS. The patients were randomised in sequential order and treatments were determined by a predefined central randomisation list.

The average duration of pain in the patient population was 7.3 years. The conditions for receiving either treatment including travelling to and from the clinic and duration of therapy were designed to be the same for both populations. Inclusion criteria for the study were: age 18-65 years; a minimum VAS score of 2; candidates must live within 45 minutes of the clinic location; capable of thoroughly understanding the information given and following protocol. All candidates signed an informed consent form.

Exclusion criteria were: osseous stenosis; unstable spine (bilateral pars defect or Spondylolisthesis of Grade II or greater); spinal surgical implants; shoulder problems which prevent compliance with VAX-D therapy; spinal pain due to tumor, infection, or inflammatory disease; pregnancy; and previous VAX-D therapy.

Patients randomised to VAX-D were treated according to the manufacturer's protocol. Patients lie on the split table device in a prone position. VAX-D utilises handgrips that the patient grasps with arms extended above the head to stabilise (restrain) the shoulder girdle and upper body. This is thought to be the most effective means of assuring that tensions applied to the pelvis are transmitted accurately along the linear axis of the spinal column during the

procedure. The fact that the patient may release at any time during the treatment provides an important safety factor. A special harness designed to apply forces primarily to the lateral pelvic alae is fitted and tightened around the patient. The pelvic harness is connected to a tensionometer at the caudal end of the table. The function of the tensionometer is to provide constant feedback to the programmed logic control and operating system. During the VAX-D session a continuous chart recording is generated plotting the controlled time/energy progress of the entire procedure.

Table 1: Demographic data

Characteristic	Statistic	All	VAX-D	TENS
No of Patients	n	44	22	22
Age (years)	Mean	42	41	43
	Range	22-57	27-57	27-55
Sex				
Female	n	21	11	10
Male	n	23	11	12
Race				
White	n	40	20	20
Asian	n	4	2	2
Chronicity				
Yrs of Pain	Mean	7.3	8.4	6.2
	Range	0.25-30	0.25-30	0.5-28

Tensions are applied to the lumbar spine in a cyclic fashion from the baseline tension up to the therapeutic range of fifty to ninety-five pounds. Each treatment session is thirty minutes in length and is comprised of fifteen cycles of decompression alternating with relaxation. Each decompression and relaxation phase may be individually varied as suitable for the particular treatment parameters.

A chart recorder prints the time energy curve for each decompression-relaxation cycle. This affords the technician a means of monitoring and adjusting the decompression process. Patients received VAX-D therapy five times per week for four weeks and then once per week for four weeks in accordance with protocol. All VAX-D treatments were administered by certified VAX-D technicians at four clinics in the Sydney area.

Patients randomised to TENS therapy received treatment at one of the four clinics. Electrodes were placed according to the manufacturer's protocol. Patients lay prone on a treatment table and received TENS for thirty minutes daily for twenty days then once a week for four weeks. All patients receiving TENS were monitored by a technician.

Neither group received any physical therapy modalities, epidural steroid injections or other treatments during the trial. Both patient groups were allowed to take non-narcotic pain relievers and anti-inflammatory medication if necessary.

A 10-cm Visual Analogue Scale (VAS) for pain and a four-point disability rating scale were used to assess patient response. The level of pain on the VAS was recorded on a 10cm line marked at one end 'No Pain' and marked at the other end 'The Worst Pain Imaginable'. The written instruction to the patient was to 'please place a mark on the line below to indicate your current level of pain'. The self-nominated disability rating scale required patients to list the four activities that were most affected by their low back pain. These were scored according to the following criteria: 1 = cannot do at all; 2 = can do but severely limited; 3 = can do but slightly limited, 4 = can do without limitation.

Data was collected at the initiation of the study prior to randomization and at the end of the eight week treatment period in a separate interview. Success was defined as (equal to or greater than) a 50% improvement in the patient's pain and any improvement in their disability rating.

Patients were free to withdraw from the study on their own volition at anytime. The study treatment could be terminated prematurely if any of the following events occurred: patient wished to terminate his/her participation for whatever cause (two cases); the investigator judged it was in the best interest of the patient to withdraw (zero cases); the patient was unable to comply with protocol (zero cases).

The efficacy-evaluable population used for statistical analysis of efficacy is comprised of all patients who were randomised to study treatment, received at least 10 study treatments, had efficacy data recorded after Baseline, and satisfied the inclusion/exclusion criteria.

The primary efficacy measure in this study was the proportion of successfully treated patients in each of the treatment groups. The difference in proportions of successfully treated patients in each treatment group was tabulated and compared using Fisher's Exact Test and 95% confidence limits.

Successfully treated patients were to be followed up at six months to determine whether the successful outcome was sustained.

Results

Forty-four patients were enrolled into the study. Twenty-two were randomised to each of the treatment groups. A summary of demographic characteristics for the 44 enrolled patients is presented in Table 1.

Two patients (4.5% of 44), Patient 029 and Patient 003, were regarded as having withdrawn/not completed the study according to the protocol. Patient 029, randomised to TENS, withdrew due to not wishing to continue and Patient 003, randomised to VAX-D, withdrew due to treatment no longer being required. No patients were withdrawn by the investigator. Patients 018 and 034 both randomised to VAX-D, did not comply with the study criteria and are therefore excluded from the efficacy-evaluable population. They both had a baseline VAS score less than 2 but this error of inclusion was not picked up until the completion of the trial. The efficacy-evaluable population therefore comprised of 40 patients: 19 patients randomised to VAX-D, 21 randomised to TENS.

A summary of the data collected at baseline and post-treatment in the efficacy-evaluable population is presented in Table 2.

Table 2: Efficacy-evaluable population

Characteristic	Statistic	VAX-D	TENS
Number of Patients	n	19	21
Number of treatments	Mean	24.1	18.0
	Range	18-36	10-24
Baseline pain (VAS)	Mean	5.99	5.44
	Range	2.1-8.7	2.7-8.5
Post treatment pain (VAS)	Mean	1.85	5.97
	Range	0-5.6	1.8-8.5
Decrease in pain (%)	Mean	69.1	-17.1
	Range	11.1-100	-123-33.3
Disability Rating			
Pretreatment	Mean	2.2	2.2
	Range	1.5-3	1.75-3
Postreatment	Mean	2.9	2.2
	Range	2.0-4.0	1.5-3
Improvement in disability rating (%)	Mean	33.8	-2.23
	Range	0-100	-36.4-50.0
Successful cases	n	13	0
	Percent	68.4	0

In the efficacy-evaluable population the proportion of successfully treated patients was 13 out of 19 patients (68.4%) for the VAX-D treatment group compared to zero out of 21 (0%) for the TENS treatment group. There was a high statistically significant treatment group comparison p-value of <0.001. The 95% confidence interval for the difference in proportions of successfully treated patients, comparing VAX-D with TENS was 47.5% to 89.3%.

In the VAX-D group all patients recorded some improvement in their pain levels whereas in the TENS group 13/ 21 recorded an increase in pain.

At six-month follow-up, of the 13 successful cases, 2 have been lost to follow-up, 1 case suffered a significant other injury and of the remaining 10, seven have shown sustained success (ie. they still meet the criteria for successful outcome).

The results reported for the TENS group were less that that expected for a placebo control. The negative outcomes may have been due to the fact that the TENS patients (and the VAX-D patients) had to travel to and attend a medical clinic five days per week for four weeks, and one day per week for four weeks. This fact that both treatment groups had to travel to, and attend the clinic, was necessary to ensure that the only variable between the two groups was in the type of treatment that they received. The benefits of treatment in the VAX-D group clearly outweighed the negative effects of travelling, which became evident in the placebo group.

Discussion

Disc stresses coupled with ongoing increased intradiscal pressures from mechanical loading may lead to failures in the normal biomechanics of the disc and progress to degeneration, posterior displacement of the nuclear material, annular disruptions and herniations. Other causative factors in the course of disc degeneration are negative diffusion gradients, reduction of the fluid content of the nucleus pulposus, and abnormal disc metabolism. With positive disc pressures throughout the day that are above diastolic pressure, the metabolism of the disc becomes anaerobic thus impeding the normal reparative healing abilities.

Proteolytic enzymes (matrix metalloproteinases) reside in the disc and have been implicated in disc degeneration. (15) The matrix metalloproteinases are regulated by specific inhibitors (TIMPS), cytokines (Interleukin-1) and growth factors. (16) Spinal loading may interfere with diffusion into the disc by reducing the gradient across the vertebral endplate. As disc metabolism becomes anaerobic, there is an accumulation of lactic acid, fall in pH, loss of chondrocyte and fibroblast function, and activation of the metalloproteinases.

Although the mechanism of action may not be fully understood the thixotrophic (17) properties of the nucleus material may facilitate nuclear migration toward the centre of the disc under negative pressures created by VAX-D.

It has been shown experimentally that elevated lactate levels and low pH in the disc prohibit disc proteoglycan synthesis and accelerates matrix degeneration (18).

Destruction of the proteoglycan matrix and fluid retention properties can lead to a degenerative cascade with loss of cellular reparative functions and vitality. The reduction of intradiscal pressures may enhance the diffusion gradient across the endplate into the avascular disc. It has been postulated that mechanisms that facilitate oxygen and nutrient uptake in the disc may exert a beneficial effect on the metabolism and restorative functions.

Successful reduction of intradiscal pressures with VAX-D therapy represents a technological advance in lumbar spinal treatment and is likely to affect both the biomechanical and biochemical causes of discogenic pain. The results from this study demonstrate that VAX-D is an effective treatment for the management of patients with chronic low back pain and is significantly superior when compared to TENS therapy. Analysis of the data demonstrated an attributable success rate of 68.4% for VAX-D. These findings are consistent with earlier studies by Gose E, Naguszewski W, Naguszewski R. (14)

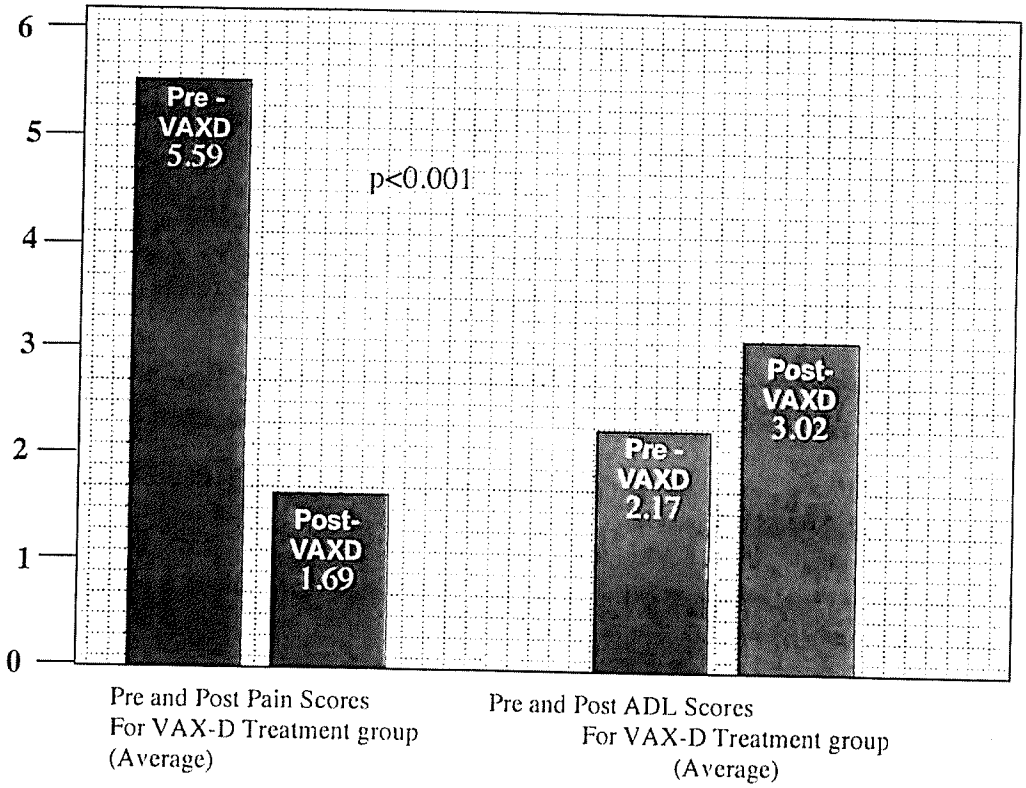
The results of this prospective study demonstrated that VAX-D can achieve a statistically significant improvement in pain and functional outcome in managing patients suffering from disc related chronic low back pain.

Acknowledgments: Australian National Musculoskeletal Initiative: For advice and instruction on the use of instruments for the outcome measures used in the present study.

Jane Ambrose, Biostatistician Quintiles: For statistical analysis of the data.

Disclosure: Dr Russell Smart is contracted to and a shareholder in VAX-D Australasia Pty Ltd, a private company that delivers VAX-D service in Australia.

Graph 1 - Results of VAX-D Treatment Group



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